

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) Publication number:

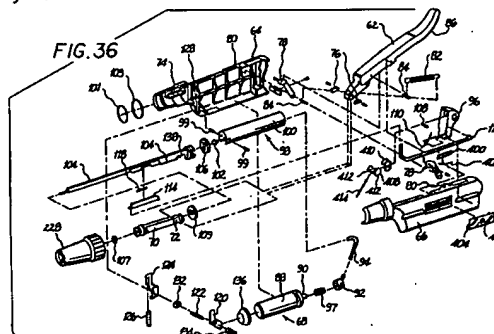
0 656 188 A2

(12)

EUROPEAN PATENT APPLICATION(21) Application number: **94115681.2**(51) Int. Cl.⁶: **A61B 17/072**(22) Date of filing: **05.10.94**(30) Priority: **08.10.93 US 134239**(43) Date of publication of application:
07.06.95 Bulletin 95/23(84) Designated Contracting States:
DE ES FR GB IT(71) Applicant: **United States Surgical Corporation**
150 Glover Avenue
Norwalk,
Connecticut 06856 (US)(72) Inventor: **Sorrentino, Gregory**
15 Nicholas Road
Wallington,
CT 06492 (US)
Inventor: **Alli, Alim**
77 Winfield Street
East Norwalk,
CT 06855 (US)(74) Representative: **Marsh, Roy David et al**
Hoffmann Eitle & Partner
Patent- und Rechtsanwälte
Arabellastrasse 4
D-81925 München (DE)(54) **Surgical apparatus for applying surgical fasteners.**

(57) A self-contained gas powered endoscopic surgical apparatus so is provided for placing lateral lines of surgical fasteners into body tissue. The apparatus includes an anvil member 56 and a surgical fastener cartridge member 58 mounted to the distal end of an elongated endoscopic portion. A tubular collar 220 of the endoscopic portion moves distally to engage the anvil member and bias the anvil member and the cartridge member into cooperative alignment, thereby clamping body tissue to be fastened between the anvil member and the cartridge member. A self contained pneumatic system 68 is optionally disposed in the surgical apparatus and is actuatable to eject and/or form the surgical fasteners in the clamped body tissue. The apparatus further comprises a locking means 176 for preventing firing of the instrument after it has been fired a predetermined number of times. A counter 400, 406, 450 for displaying the number of times the apparatus has been fired may be provided. A firing interlock is also shown which prevents accidental actuation of

the firing trigger. A clamping interlock 408, 410 is shown which prevents approximation of the jaws when the jaws are either misaligned or improperly inserted into the instrument. The instrument also includes means 480 for disabling the actuation system after a cartridge has been fired and means 490 for identifying a cartridge member having firing characteristics compatible with the pneumatic actuation system.

**EP 0 656 188 A2**

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to surgical stapling apparatus, and more particularly to surgical apparatus to perform sequential operations such as tissue clamping, staple forming and/or tissue cutting.

2. Description of Related Art

Surgical stapling apparatus is known wherein tissue is first grasped or clamped between opposing jaw structure and then fastened by means of fasteners. In some instruments a knife is provided to cut tissue which has been joined. The fasteners are typically in the form of surgical staples; however, two part polymeric type fasteners are also known.

Instruments for this purpose can comprise two elongated fingers which are respectively used to capture or clamp tissue. Typically, one of the fingers carries a disposable cartridge housing a plurality of staples arranged in at least two lateral rows while the other finger comprises an anvil for curling the staple legs into hook form upon their being driven against the anvil. The stapling operation is effected by a cam bar which travels longitudinally along the cartridge carrying finger, acting on transversely mounted pushers which in turn act upon the staples to place rows of staples in body tissue. A knife may optionally be positioned to operate sequentially immediately behind the cam bar and laterally positioned between the staple rows to longitudinally cut and/or open the stapled tissue between the rows of staples. Such instruments are disclosed in U.S. Pat. No. 3,079,606 to Bobrov et al. and U.S. Pat. No. 3,490,675 to Green. The instruments disclosed therein comprise apparatus for simultaneously making a longitudinal incision and applying a row of staples on both sides of an incision.

A later development disclosed in U.S. Pat. No. 3,499,591 to Green applies a double row of staples on each side of the incision. This is accomplished by a cartridge assembly wherein a cam member moves within a guide path between two sets of staggered staple carrying grooves. Staple drive members located within the grooves each have two staple pusher plates, and sloping surfaces disposed within the guide path so as to be contacted by the longitudinally moving cam and be driven along the groove to effect ejection of two staples.

The cartridge assemblies typically come in a plurality of sizes, each varying in wire diameter, staple size and number of staples contained therein. Depending on the procedure to be performed, the surgeon must select the appropriate cartridge

assembly. The instruments described above were all designed to be used in surgical procedures wherein surgeons have direct manual access to the operation site. However, in endoscopic or laparoscopic procedures surgery is performed through a small incision or through narrow canulae inserted through small entrance wounds in the skin. In order to address the specific needs of endoscopic and/or laparoscopic surgical procedures, endoscopic surgical stapling apparatus such as that shown in U.S. Pat. No. 5,040,715 to Green et al. have been developed. This apparatus is well suited for such procedures and incorporates a distal end having an anvil and staple cartridge assembly and a manually operated handle assembly interconnected by an endoscopic portion which permits the instrument to be inserted into a cannula and be remotely operated by the surgeon.

The instruments discussed above all require some degree of manually applied force in order to clamp, fasten and/or cut tissue. This manual application can prove awkward or difficult depending upon the orientation of the instrument relative to the surgeon, the type of tissue being operated on, the number of staples to be placed or the strength of the surgeon. Furthermore, because of the difficulty and expense of cleaning and sterilizing surgical instruments between uses, there is increasing interest in and demand for instruments which are disposable after use in a single surgical procedure rather than permanent and reusable. And because of the greater convenience and ease of using self-powered instruments as well as the more uniform results typically produced by self-powered instruments (as compared especially to manually powered instruments), there is increasing interest in and demand for instruments which are self-powered.

Therefore, it is one object of the present invention to provide a self contained gas powered surgical apparatus for driving fasteners into body tissue.

It is a further object of the present invention to provide a self contained gas powered surgical apparatus insertable through a small incision or narrow tube for driving surgical fasteners into body tissue and cutting the body tissue between rows of staples.

Another object of the present invention is to provide a self contained gas powered surgical apparatus which is disposable after use.

A further object of the present invention is to provide a self contained gas powered surgical apparatus having a gas metering element to prevent firing of the staples from the cartridge unless a sufficient quantity of gas is available to move the driving member through a full sequence of operation.

Another object of the present invention is to provide a surgical apparatus having a clamping lockout mechanism which will prevent clamping of tissue unless the cartridge has been properly inserted in the instrument.

A further object of the present invention is to provide a self contained gas powered surgical apparatus having sealing structure for inhibiting the escape of gas through the apparatus.

Another object of the present invention is to provide a self contained gas powered surgical apparatus having counter structure for displaying the number of times the instrument may be fired.

A further object of the present invention is to provide a self contained gas powered surgical apparatus with lockout structure to disable the apparatus after a predetermined number of firings.

Another object of the present invention is to provide a self contained gas powered surgical apparatus having a unique counter mechanism which indicates the number of times the apparatus may be fired and which prevents firing of the apparatus after a predetermined number of firings.

A further object of the invention is to provide a surgical apparatus which disables an actuation mechanism in the absence of an unfired fastener cartridge.

Another object of the invention is to provide a surgical apparatus which will disable an incompatible fastener cartridge upon loading to prevent firing of the incompatible cartridge in the apparatus.

SUMMARY OF THE INVENTION

The objects of the subject invention are accomplished in accordance with the principles of the invention by providing a surgical instrument which is either manually operated in its entirety or at least partially operable by means of a relatively low pressure pneumatic assembly. Advantageously, the surgical instrument in accordance with an embodiment of the present invention is a surgical stapling apparatus adapted for placing one or more longitudinal rows of staples. This apparatus may further include a knife for making an incision in body tissue between rows of staples. The latter configuration may find particular use of adjoining two hollow organs or in removing an organ, such as the appendix, the gallbladder, etc.

The surgical instrument of the present invention in an endoscopic stapler configuration comprises a frame; an endoscopic portion defining a longitudinal axis and extending distally from the frame, the endoscopic portion including an elongated housing having a distal member for mounting a cartridge assembly. The cartridge assembly includes a plurality of surgical staples slidably mounted therein and has a tissue engaging surface. An

anvil member is also provided and has a staple forming surface and a proximal end mounted to the elongated housing such that the anvil member is movable between an open position and a closed position such that the staple forming surface is in close cooperative alignment with the tissue engaging surface of the cartridge assembly.

The instrument further includes structure for moving the anvil member between the open and the closed positions and structure for ejecting the surgical staples from the cartridge assembly to cause the staples to engage and form on the staple forming surface of the anvil member. The instrument also optionally includes a self contained pneumatic system which is disposed in the frame and includes a supply of relatively low pressure gas which is connected to a pneumatic actuator mechanism. The pneumatic actuator mechanism actuates the structure for ejecting the surgical staples from the cartridge assembly.

The surgical instrument of the subject invention may be constructed either as a reusable unit or as a single use, disposable unit or, alternatively may be formed with a reusable handle portion and replaceable staple carrying cartridges. The present invention advantageously permits surgeons to perform internal surgical procedures including stapling and/or cutting simply by manually clamping the tissue to be manipulated and either manually or pneumatically actuating the jaw members. The pneumatic actuation embodiment may result in greater convenience and ease of use of the instrument as well as more uniform actuation of the instrument mechanisms.

The pneumatically actuated stapler embodiment of this invention is preferably controlled by a manually operable trigger or other similar control. Momentary operation of the trigger initiates an operating cycle of the stapler which is automatically completed without continued actuation of the trigger. A safety interlock may also be employed in cooperation with the trigger mechanism to prevent accidental actuation. Preferably the stapler performs only one operating cycle in response to each operation of the control regardless of the length of time the control is operated beyond the time required to initiate an operating cycle. The stapler will not begin a new operating cycle until the preceding cycle has been completed.

In a preferred embodiment of the subject invention, a safety mechanism may be incorporated in either a pneumatically actuated or manually actuated apparatus to prevent closure of the jaws if they are misaligned or improperly inserted. In addition, a mechanism may be provided to prevent the user from loading an inappropriate stapling cartridge into the instrument.

In another preferred embodiment of the invention, the operating cycle of a pneumatically actuated apparatus will not begin unless sufficient gas remains in the reservoir to propel the instrument through a complete cycle. Alternatively, structure may be provided to give a visual or tactile indication of the number of times the instrument has been fired and/or lock out the operating cycle after a given number of firings. The counter structure may also be configured to indicate the number of times the instrument can be fired. Preferably, the counter structure is operatively associated with the pneumatic actuation system and will inhibit the actuation thereof after a predetermined number of operations.

In another advantageous embodiment of the invention the surgical element includes adjustment structure which permits the instrument to be selectively preset to fire in a predetermined sequence to drive a given number of staples and/or rows of staples.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawing and the following detailed description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described hereinbelow with reference to the drawings wherein:

Fig. 1 is a perspective view of a self contained gas powered endoscopic surgical instrument with which the present invention may be beneficially employed;

Fig. 2 is an exploded perspective view of the frame and pneumatic assembly of the surgical instrument of Fig. 1;

Fig. 3 is an exploded perspective view of the endoscopic portion of the surgical instrument of Fig. 1;

Fig. 3A is a side plan view in partial cut away of the pusher washers and flange member of the pneumatic system in accordance with an embodiment of the surgical instrument of Fig. 1;

Fig. 4 is an exploded perspective view of one embodiment of the anvil and cartridge assembly of the surgical instrument of Fig. 1;

Fig. 5 is a side plan view in cross section taken along line 5-5 of Fig. 1 showing the frame and pneumatic assembly in the unclamped and unfired position;

Fig. 6 is a transverse view in cross section taken along line 6-6 of Fig. 5 oriented toward the proximal end of the instrument showing the frame and pneumatic assembly in the unclamped position;

Fig. 7 is a side plan view in cross section showing the frame and pneumatic assembly of the surgical instrument of Fig. 1 in the clamped and unfired position;

Fig. 8 is a transverse view in cross section taken along line 8-8 of Fig. 7 oriented toward the proximal end of the instrument showing the frame and pneumatic assembly in the clamped and unfired position;

Fig. 9 is a top plan view in cross section taken along line 9-9 of Fig. 5 showing the frame and pneumatic assembly of the surgical instrument; Fig. 10 is a transverse view in cross section taken along line 10-10 of Fig. 5 oriented toward the distal end of the instrument showing a portion of the frame and pneumatic assembly;

Fig. 11 is a side plan view in cross section showing the frame and pneumatic assembly of the surgical instrument of Fig. 1 in the clamped and fixed position;

Fig. 12 is a side cut away view in cross section showing the operation of the pneumatic assembly of the surgical instrument of Fig. 1 as it is fired;

Fig. 13 is a side cut away view in cross section taken along line 13-13 of Fig. 12 showing the valve and gas tube of the pneumatic assembly;

Fig. 14 is a side plan view in cross section showing the frame and pneumatic assembly of a surgical instrument incorporating an adjustable stroke mechanism;

Fig. 15 is a side cut away view in cross section of a surgical instrument incorporating a metering assembly between the valve and piston assembly;

Fig. 16 is a side plan view of a channel member of the surgical instrument of Fig. 1;

Fig. 17 is a transverse view in cross section taken along line 17-17 of Fig. 16 oriented toward the proximal end of the channel member;

Fig. 18 is a transverse view in cross section taken along line 18-18 of Fig. 16 oriented toward the distal end of the channel member;

Fig. 19 is a bottom plan view of an anvil member of the surgical instrument of Fig. 1;

Fig. 20 is a top plan view of the anvil member of Fig. 19;

Fig. 21 is a side view of the anvil member of Fig. 19;

Fig. 22 is a top plan view of a cam bar adaptor of the surgical instrument of Fig. 1;

Fig. 23 is a side plan view of the cam bar adaptor of Fig. 22;

Fig. 24 is a front plan view of the cam bar adaptor taken along line 24-24 of Fig. 22 oriented toward the proximal end of the adaptor;

Fig. 25 is a side plan view in cross section of the cartridge housing of Fig. 4;

Fig. 26 is a top plan view of the cartridge housing shown in Fig. 25;

Fig. 27 is a side cut away view in cross section of the cartridge housing of Fig. 25 taken along line 27-27 of Fig. 26;

Fig. 28 is an exploded perspective view of a cartridge assembly of the surgical instrument of Fig. 1;

Fig. 29 is a perspective view of the assembled cartridge assembly of Fig. 28;

Fig. 30 is a perspective view in partial cross section of an anvil and cartridge assembly of the surgical instrument of Fig. 1;

Fig. 31 is a perspective view in partial cross section of an anvil in accordance with the embodiment of Fig. 30;

Figs. 32 through 34 are side plan views in partial cross section of a sequence of operations for the anvil and cartridge assembly of Fig. 30;

Fig. 35 is a perspective view of another self contained gas powered surgical instrument with which the present invention may be beneficially employed;

Fig. 36 is an exploded perspective view of the handle portion of the self contained gas powered surgical instrument of Fig. 35;

Fig. 37 is an exploded perspective view of the endoscopic portion and jaw structure of the self contained gas powered surgical instrument of Fig. 35;

Figs. 38 and 39 are side cross-sectional views of the firing trigger with integral lockout in the unfired and fired positions of the surgical instrument of Fig. 35;

Figs. 40 and 41 are side views of the cartridge and support structure of the surgical instrument of Fig. 35 showing the operation of the clamp lockout structure;

Fig. 42 is a side elevational view in partial cross-section of the frame portion of the self contained gas powered surgical apparatus of the subject invention which includes a unique counter mechanism for indicating the number of times the surgical apparatus has been fired;

Fig. 43 is a perspective view in partial cross-section of the frame portion illustrated in Fig. 42 with the plunger advanced distally during a firing operation;

Fig. 44 is a side elevational view in partial cross-section of the frame portion illustrated in Fig. 42 with the counter mechanism indexed in response to the firing operation illustrated in Fig. 43;

Fig. 45 is a side elevational view in partial cross-section of the frame portion illustrated in Fig. 42 with the counter mechanism indexed through four firing operations to lock the trigger mechanism;

Fig. 46 is an enlarged partial break-away view of the distal end portion of the apparatus;

Fig. 47 is an enlarged partial break-away view similar to Fig. 46 illustrating the channel stop engaged with channel stop abutment member;

Fig. 48 is a partial perspective view of a pneumatic actuation system in accordance with the present invention;

Fig. 49 is a partial perspective view similar to Fig. 48 illustrating the trigger rod engagement member in position behind the rocking lever; and

Fig. 50 is an enlarged partial perspective view illustrating cartridge identifier structure in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

It is generally accepted that endoscopic procedures are more common than laparoscopic procedures. Accordingly, the present invention shall be discussed in terms of endoscopic procedures and apparatus. However, use herein of terms such as "endoscopic", "endoscopically" and "endoscopic portion", among others, should not be construed to limit the present invention to a stapling and cutting apparatus for use only in conjunction with an endoscopic tube. To the contrary, it is believed the present invention may find use in any procedure where access is limited to a small incision, including but not limited to laparoscopic procedures. Also, as used herein the terms "fasteners" and "staples" shall be treated equivalently. Unless otherwise stated, the term "cartridge assembly" shall include at least the cartridge itself and staples or fasteners and staple drive members disposed therein.

In the drawings and the description which follows, as is traditional, the term "proximal" will refer to the end of the instrument which is closest to the operator while the term "distal" will refer to the end of the instrument which is furthest from the operator.

Although the principles of the invention are applicable to other types of manually and pneumatically actuated surgical fastening instruments, the invention will be fully understood from the following illustration of its application to endoscopic surgical fastening instruments, including specifically, but without limitation, apparatus of the type disclosed, in U.S. Patent No. 5,040,715 to Green et al., the contents of which are incorporated herein by reference. Also, although the invention is applicable to surgical fastening apparatus having other constructions, the invention will be illustratively described in its application to surgical staplers in which a staple cartridge containing a plurality of

staples, staple drivers and staple firing means in cooperation with anvil means respectively form opposing jaw structure located on a distal end of the stapler for capturing and joining tissue.

As shown in Fig. 1, a self contained gas powered endoscopic surgical instrument 50 which may beneficially employ the principles of this invention includes a frame 52 and an endoscopic portion 54. An anvil 56 and cartridge assembly 58 are mounted in a distal end 60 of endoscopic portion 54 and are preferably interchangeable with other anvil/cartridge assemblies (as discussed in greater detail hereinbelow) to perform a wide variety of surgical fastening procedures as needed.

Anvil 56 and cartridge assembly 60 are manually controlled by means of an articulating handle 62 in the frame 52. This handle 62 interconnects with anvil 56 by means of a linkage disposed in endoscopic portion 54 such that when handle 62 is moved from its open position (Fig. 1) to a closed position (Fig. 7), anvil 56 is moved into close approximation with cartridge assembly 58. This operation will be discussed in greater detail below.

Turning now to Fig. 2, an exploded perspective view of the frame and pneumatic system is shown. Frame 52 includes a first housing member 64 and a second housing member 66 enclosing a pneumatic system shown generally at 68. Articulating handle 62 is pivotally connected at a distal end thereof to clamp tube 70 at pivot point 72. Longitudinal grooves 74 formed in both first and second housing members 64, 66 adjacent pivot point 72 slidably receive molded shuttles 76 attached to handle 62 at 72. The molded shuttles 76 are pivotally connected to either side of the pivot point 72 on the distal end of handle 62 and serve to guide the distal end of handle 62 in a longitudinally distal direction as the handle is compressed.

A pair of articulating links 78 interconnect an intermediate portion of handle 62 to a pair of projections 80 formed on an upper surface of housing members 64, 66 respectively. A handle return spring 82 extends between handle 62 and housing members 64, 66 by means of spring anchor pins 84, one of which is disposed in handle 62 and the other extending between projections 80 which also serve to pivotally connect articulating links 78 to projections 80. This spring 82 assists in returning handle 62 from its closed position to its open position.

The proximal end of handle 62 is preferably diagonally formed away from housing members 64, 66 so as to enable the surgeon to more easily release the handle 62 from its closed position. This is done by placing the hand under the proximal end of the handle and lifting. A texturized or serrated portion 86 may advantageously be formed on an under surface of the proximal end of handle 62

to enhance gripping of the handle 62.

Pneumatic system 68 is wholly contained within housing members 64, 66 and includes a container 88 of relatively low pressure gas longitudinally slidably mounted therein. The pressure of the gas in container 88 during operation of the stapler is typically less than about 200 p.s.i.g. and preferably in the range from about 80 p.s.i.g. to about 160 p.s.i.g. Any suitable non-toxic gas can be used including but not limited to halogenated hydrocarbons which are gaseous at room temperature, e.g., fluorinated hydrocarbons such as Freon 12 or chlorinated hydrocarbons such as Freon 152A. Container 88 dispenses the relatively low pressure gas through stem 90, valve 92 and gas tube 94 when the firing trigger 96 is depressed. Spring 97 is positioned between container 88 and valve 92 and serves to hold the container 88 away from valve 92. Valve 92 is fixed within housing members 64, 66 and is longitudinally adjustable by means of set screw 93. (Fig. 13) This feature permits the position of valve 92 to be longitudinally changed to compensate for manufacturers' variations in length among containers 88 between a distal end and the proximal end of stem 90.

Disposed above container 88 within housing members 64, 66 is a pneumatic actuator 98. Actuator 98 includes a pneumatic cylinder 100 which is held in place by opposing pins 99 and which is closed at its proximal end except for ferrule 102 and is open at its distal end, as well as a pneumatic piston 104 mounted for reciprocal motion in cylinder 100 parallel to the longitudinal axis of endoscopic portion 54. Cylinder 100 is preferably circular in transverse cross-section however other shapes would function acceptably well.

Piston 104 is pneumatically sealed to cylinder 100 by "O" ring 106 molded of polyethylene or the like. Gas dispensed from container 88 is supplied to pneumatic actuator 98 via gas tube 94 which admits the gas to cylinder 100 through ferrule 102 behind piston 104 to drive piston 104 distally in the cylinder. The distal end of piston 104 is adapted to engage the firing mechanism of the surgical apparatus as will be described in greater detail below.

Referring to Figs. 2, 5 and 7, firing trigger 96 is pivotally mounted in a proximal end of housing member 64, 66 by pivot pin 108. Spring 110 is positioned adjacent pin 108 and serves to bias the firing trigger 96 proximally into the prefiring position. A trigger rod 112 extends distally from firing trigger 96 longitudinally to engage piston slide 114 positioned in a lower portion of piston 104. Piston slide 114 comprises a substantially "U"-shaped channel which fits into a corresponding groove 116 formed in piston 104. Piston slide 114 is spring loaded in a proximal direction by spring 118 and includes a transverse projection 120 on a lower

distal end thereof which engages the distal end of trigger rod 112.

Referring now to Figs. 2 and 5-11 and initially to Figs. 2, 5-8 and 11, a rocking lever 120 is pivotally mounted on transverse slide pin 122 and is adapted for transverse movement relative to slide pin 122 between an engaged position prior to firing (Figs. 7-9) and a disengaged position when articulating handle 62 is open (Figs. 5 and 6). Cam slide 124 is vertically mounted in first housing member 64 for reciprocal movement between an upper and lower position (Figs. 6 and 8 respectively) and serves to move rocking lever 120 between the engaged position (Fig. 8) and the disengaged position (Fig. 6). Thus, until the articulating handle 62 is closed causing cam slide 124 to move rocking lever 120 into the engaged position, the instrument 50 cannot be fired.

Cam slide 124 is normally biased in its upper disengaged position by cam slide spring 126 mounted in vertical groove 128 of first housing member 64 (Figs. 5 and 6). In this upper position, cam slide 124 extends upward beyond first housing member 64 (Fig. 6) to engage articulating handle 62 as it is moved to a closed position (Figs. 7 and 8). Cam slide 124 further includes a camming surface 130 which contacts a corresponding camming surface of camming block 132 mounted on slide pin 122. Camming block 132 is loaded against cam slide 124 by slide spring 134 and moves rocking lever 120 transversely on slide pin 122 between an engaged position and a disengaged position. Referring to Fig. 8, as the articulating handle 62 is compressed toward housing members 64, 66 in the direction of arrow 135 it contacts cam slide 124 moving it downward and causes camming surface 130 to move camming block 132 and rocking lever 120 transversely into an engaged position in line with piston 104.

Turning to Figs. 5, 7-9 and 11, once the articulating handle 62 has been fully compressed (Figs. 7-9) rocking lever 120 is disposed in alignment with piston slide 114 and can be pivotally moved about transverse slide pin 122 to engage pusher disk 136 at the distal end of container 88. When the instrument is in the clamped configuration, depression of the firing trigger 96 moves trigger rod 112 distally in the longitudinal direction causing piston slide 144 to engage and pivot rocking lever 120 which, in turn, engages pusher disk 136 and moves container 88 longitudinally into contact with valve 92 to dispense gas and propel piston 104 in the distal direction. See Figs. 11, 12 and 13.

As piston 104 moves distally, rocking lever 120 remains in its pivoted firing position by contact with the bottom surface of piston 104. A gap 138 is formed in the bottom surface of piston 104 near the proximal end thereof which gap effectively allows

rocking lever 120 to disengage from piston 104 and pivot back to a position wherein container 88 is released from engagement with valve 92, stopping the flow of gas into pneumatic cylinder 100.

Return springs 140, 142 disposed in endoscopic portion 54 drive piston 104 back to its initial prefired position. A camming surface 144 is formed in a distal end of gap 138 and causes rocking lever 120 to move transversely out of engagement with piston 104 as it returns proximally and the rocking lever 120 moves to its original prefired position (Fig. 7).

Fig. 14 shows a second surgical instrument which may benefit from the present invention which incorporates an adjustment mechanism 146 which permits the instrument 148 to be selectively adjusted to change the length of the firing and return strokes of piston 150. This advantageous feature permits the user to selectively fire a predetermined length of staples using a single instrument. For example, if the user installs a staple cartridge assembly having six rows of staples, each row having a longitudinal length of 60 mm, the instrument is set using adjustment mechanism 146 to fire the staples in the entire length of the cartridge. Cartridges having some lesser length of staples may be inserted and fired depending on the needs of the user.

The adjustment mechanism 146 shown in Fig. 14 includes a belt 152 which travels around a pair of longitudinally disposed pulleys 154, 156. A first linkage rod 158 engages the top portion of belt 152 and extends to a gap adjustment member 160 slidably positioned in piston 150. A second linkage rod 162 engages the bottom portion of belt 152 and extends to a slidable piston stop 164 disposed within pneumatic cylinder 100.

Belt 152 may be rotated in either the clockwise or counterclockwise direction by rotating knob 166 disposed in housing 172 between pulleys 154 and 156. This permits the user to preselect the firing stroke of the instrument 148. For example when belt 152 is rotated counterclockwise, the firing stroke piston stop is being driven proximally by second linkage rod 162 and the gap 168 wherein the rocking lever 120 disengages the pneumatic actuator 98 is correspondingly widened. This permits the user to fire shorter rows of staples without changing cartridge assemblies. Conversely, when belt 152 is rotated in a clockwise direction, the firing stroke is progressively lengthened this allowing the user to fire up to the entire length of the rows of staples in the cartridge assembly.

In the instrument 148 shown in Fig. 14, the firing stroke may be preset to fire either 30 mm or 60 mm rows of staples from a 60 mm length cartridge assembly. These preset positions correspond to camming pins 186 and 170 respectively

which serve to disengage first rod linkage 158 from belt 152 so that belt 152 is not rotated during the firing stroke of the pneumatic actuator 98.

Turning now to Fig. 15, a pressure sensor 174 is disposed in line between the valve 92 and the pneumatic cylinder 100 to sense and/or regulate the gas delivered from container 88 to the cylinder 100. During surgical procedures involving the driving of surgical fasteners and particularly where a knife is used to divide fastened tissue, it is important that when the trigger is depressed there is sufficient gas remaining in the container 88 to complete an entire piston firing stroke. If insufficient gas were available, the piston may not be able to fasten and/or divide the desired length of tissue, necessitating duplication of the procedure. Pressure sensor 174 serves to premeasure the amount of gas necessary to achieve the desired piston stroke before activating to permit the gas to flow into the pneumatic cylinder 100 to drive piston 104.

It is also envisaged that a counter mechanism can be incorporated to operate in conjunction with the pneumatic system 68 in order to monitor the number of firings which the instrument has been subjected to. This number can be visually displayed to the operator so that, for example, after a given number of firings, the instrument can be overhauled or replaced. Similarly, where a relatively small number of firings are available from a single gas container, this counter mechanism will assist the operator in recognizing when the container is nearing exhaustion. In a particularly desirable embodiment, the counter mechanism can be combined with a lockout mechanism which will disable the firing mechanism after a preselected number of firings.

As seen in Fig. 15, upon depressing firing trigger 96, gas is released from container 88 substantially as described hereinabove. However, after leaving stem 90 and passing through nozzle 92, the gas contacts pressure plate 176. Pressure plate 176 is preset by means of spring 178 to keep orifice 180 closed until a predetermined gas pressure is realized at the pressure plate 176. Once this threshold pressure is realized, pressure plate 176 moves out of contact with orifice 180 permitting gas to pass therethrough and into pneumatic cylinder 100 to drive piston 104 distally. In the event that insufficient gas is available to reach this threshold pressure, pressure plate 176 continues to block orifice 180 and the instrument cannot be fired.

Referring now to Fig. 3, there is shown in exploded detail an endoscopic portion 54 of a surgical instrument which may beneficially employ the present invention. At a proximal end, piston 104 is longitudinally reciprocally slidable through clamp

tube 70 and extends into the proximal end of cover tube 182. The distal end of piston 104 is provided with an attachment flange 184 which flange 184 mounts a plurality of pusher washers 186 thereon. These pusher washers 186 are formed in a substantially abbreviated frustoconical cross-section from a resilient material such as, for example, commercial spring steel or type 302 stainless steel. These washers are typically known as Belleville Spring Washers available through SPEC Associated Spring Raymond, Barnes Group Inc. The washers are especially suited for high loads in small spaces and may be combined in varying sequences to achieve numerous load carrying possibilities. In the embodiment of Fig. 3, a total of twelve pusher washers are used substantially as shown in Fig. 3A with duplicate washers arranged in six opposing sets. A spring support washer 188 is positioned on flange 184 distal to pusher washers 186 and serves to engage the proximal ends of inner and outer return springs 140 and 142. Lock washer 189 holds the washers in place on flange 184. Attachment flange 184 has a chamfered distal tip and is configured and dimensioned to be received between the proximal fingers 190 and channel 192.

As shown in Figs. 3 and 16-18, channel 192 is an elongated structure slidably mounted in endoscopic portion 54 for reciprocal longitudinal motion therein. As mentioned above, channel 192 has fingers 190 at a proximal end thereof to receive attachment flange 184 of piston 104. At a distal end of channel 192 there is provided a fork 194 defining a slot 196 therebetween. Fork 194 has a pair of opposed ramping surfaces, 198 and 200 respectively, the purposes of which will be described in greater detail below. Proximal to fork 194 is abutting structure 202 which structure extends below the lowermost dimension of fork 194.

Referring back to Fig. 3, an extension sleeve 204 is disposed within the cover tube 182 and is fixed on a proximal end thereof to clamp tube 70. Sealing member 206 is mounted on flange 208 of clamp tube 70 and serves to sealably isolate the frame 52 of the instrument 50 from the endoscopic portion 54. Inner and outer return springs, 142 and 140 respectively, are contained within upper extension spacer 210 and lower extension spacer 212 which are, in turn, fixed within the extension sleeve 204. Spring support washer 188 abuts the proximal ends of inner and outer return springs 142 and 140 and, when the instrument is fired, transmits the energy of the compressed springs 142, 140 to the piston 104, returning it to its prefired position.

Support structure 214 is also disposed within extension spacers 210, 212 and function to releasably receive anvil and/or cartridge assemblies in instrument 50. Support structure 214 is retained in

place within extension spacers 210, 212 by transverse support key 216. An anvil return spring 218 is affixed to an underside portion of support structure 214 and assists in the retention of the anvil within the instrument.

A collar assembly, shown generally at 220, is attached to the respective distal ends of external sleeve 204 and extension spacers 210, 212. This assembly 220 includes a forward collar tube 222, a collar tube spacer 224 and a rear collar tube 226, each having camming bosses 268, 270 formed on inner surfaces therein as will be described in greater detail below.

In the instrument shown in Figs. 1-3, the endoscopic portion 54 is rotatable relative to the frame 52 by means of rotation knob 228 (Figs. 1 and 2). This rotation knob 228 is in the form of an abbreviated frustoconical structure having a bore therethrough dimensioned to receive a proximal end of cover tube 182. At a proximal end of knob 228, knurling 229 may be provided to facilitate rotation. Once connected to cover tube 182, rotation of knob 228 causes the distal working end of the instrument to rotate.

Referring now to Figs. 4 and 19-27, there is illustrated an anvil 230 and cartridge assembly, shown generally at 232, in accordance with one embodiment of the present invention. Anvil 230 is an elongated piece which is mounted in support 214 by means of proximal legs 250. At its distal end, anvil 230 has an anvil plate 236 with a tissue contacting surface 238 having staple forming depressions 240 (See Fig. 19). At its proximal end, anvil 230 is provided with an upper camming surface 242 and locking surface 244, which surfaces are engagable with corresponding top arcuate camming surface 246 formed in forward collar tube 222. Transverse opposing projections 248 are formed on legs 250 at the proximal end of anvil 230 and provide an engagement point for anvil 230 to be cammed between an open and closed position by the interaction of camming surface 242, locking surface 244 and top arcuate camming surface 246 of collar tube 222. Preferably, the radius of curvature of the top arcuate camming surface 246 is shorter than the radius of curvature of camming surface 242 and equal to the radius of curvature of locking surface 244. This configuration prevents flexing of the camming surface 246 of collar tube 222 and lateral movement of the anvil as it is being cammed closed.

Anvil plate 230 also has a longitudinal center groove 252 to permit passage of a knife 254. Anvil 230 is further provided with parallel aligning surfaces 256 positioned below camming surface 242. These aligning surfaces are dimensioned to fit outside projections 258 on cartridge housing 260 upon closure of the anvil 230. The engagement of the

aligning surfaces 256 and the corresponding projections 258 of cartridge housing 260 serves to more accurately and securely align anvil 230 and cartridge housing 260 upon closure. Further visual confirmation of alignment is facilitated by a pair of parallel longitudinal indentations 262 formed in the distal end of anvil 230. These indentations 262 allow the surgeon to view the closed structure of the anvil 230 and cartridge assembly 232 to confirm accurate longitudinal alignment thereof.

Further, as shown in Fig. 21, the horizontal plane formed by tissue contacting surface 238 intersects the horizontal plane formed by the camming portion of the proximal end of anvil 230 at an obtuse angle "a". This angular orientation pre-cambers the anvil 230 and balances the closure force applied by the anvil 230 to the captured tissue.

First and second camming surfaces, 264 and 266 respectively, are formed in a sidewall portion of the proximal end of anvil 230. These camming surfaces engage camming bosses, 268 and 270 respectively, formed on inner opposing sidewalls of collar tube assembly 220. Anvil 230 is inserted into collar tube assembly 220 and projections 248 engage with support structure 214 bring camming surfaces 264 and 266 into engagable alignment with camming bosses 268 and 270. Cartridge assembly 232, discussed in greater detail hereinbelow, is fixedly inserted into collar tube assembly 220 and remains stationary relative to anvil 230.

During fabrication of anvil 230, the anvil blank may advantageously be formed by metal injection molding and thereafter coined and coated as described below. A wide variety of staples and fasteners are contemplated for use with the present apparatus. In a preferred embodiment for use with titanium fasteners, it has been found that forming of the fasteners in the staple forming depressions 240 is facilitated by applying a hard, relatively smooth surface on the staple forming portion of the anvil 230. The preferred method of application of this surface is by electroless plating, with the surface being formed of a metallic alloy such as, for example, nickel, gold, silver, titanium nitride or chromium. Where nickel is used, the applied surface is preferably in the range of 100 μ - 2000 μ in thickness with an optimum thickness of between 200 μ - 500 μ . Ranges for other alloy may vary depending upon their inherent characteristics.

Where nickel is to be applied, the preferred method is an electroless plating method including the steps of: electrocleaning the anvil in a cyanide-containing cleaner, reversing polarity at predetermined intervals, preferably about every 10-15 seconds, at a current of about 50 amps/ft²; rinsing thoroughly; rinsing in a solution containing a strong acid, preferably 20% HCL, dipping several times; immersing the anvil in a NiCL strike tank for plat-

ing, preferably for two to four minutes at a current of about 50 amps/ft²; rinsing; and immersing the anvil in an electroless Ni bath, preferably Enthone 418 or 431, for a time sufficient to achieve the desired plating thickness. For example, at a deposition rate of .0005 in/hr, a time of between 30 to 40 minutes would be required to achieve a thickness of about 300 $\mu \pm 50 \mu$. Other coating procedures are also contemplated including vapor deposition, etc. and are encompassed by the present invention.

Turning now to Figs. 4 and 22-27, there is illustrated a replaceable cartridge assembly 232. The cartridge assembly 232 includes: a cartridge housing 260; a cartridge 272 having a plurality of pushers 274 and staples 276 disposed in longitudinal arrangement therein; and a plurality of cam bars 278 removably disposed in cam bar adaptor 280 and a cam bar alignment tab 282 as well as a knife 254 mounted in the cam bar adaptor 280.

Referring specifically to Figs. 25-27, the proximal end of cartridge housing 260 comprises a substantially elongate channel of semi-circular cross-section having a forward and rearward portion 284 and 286 respectively. A transverse locking slot 288 is formed in rearward portion 286 and serves to engage and retain support structure 214. Upon insertion into collar tube assembly, the forward end of support structure 214 is biased by the rearward portion 286 of cartridge housing 260 until the support structure 214 engages locking slot 288.

Rearward projection 290 is formed in the base of cartridge housing 260. The function of this projection 290 will be described in greater detail below. Forward of the projection 290 is a bore 292 which receives shear pin 294 formed on cam bar adaptor 280 (Figs. 22-24). A pair of crimps 296 is provided in opposing sidewalls of the rearward portion of the proximal end of the cartridge housing. These crimps 296 provide a friction fit with cam bar adaptor 280.

The forward portion 284 of the proximal end of cartridge housing 260 has projections 258 which, upon closure of the cartridge assembly 232 and anvil 230, contact and align with anvil aligning surfaces 256 as described above.

The distal end of the cartridge housing 260 comprises a channel structure of substantially rectangular cross-section. This distal end constitutes the cartridge receiving portion and is dimensioned to receive cartridge 272 therein. Bores 298 and projection 300 serve to engage pins and bores respective in the cartridge 272 so as to align and retain the cartridge 272 within the cartridge receiving portion of the cartridge housing 260.

Referring to Fig. 26, the cartridge receiving portion in the distal end of cartridge housing 260 and the proximal end of cartridge housing 260 are

joined at an obtuse angle - defined by the intersection of the horizontal planes of both the proximal and distal ends of the cartridge housing 260. This angular orientation serves to pre-camber the cartridge assembly and facilitates accurate closure and alignment of the jaw elements as well as more secure retention of subject tissue.

The cartridge 272 includes longitudinal groove structure 302 for receiving and guiding knife 254 and a plurality of pushers 274 abutting staples 276. The staples 276 are advantageously arranged in six longitudinal rows with three rows positioned on either side of groove structure 302.

Two pairs of longitudinal slots are formed in the cartridge housing 260 and are adapted to receive a pair of double cam bars 278 therein. Each pair of cam bars serving to drive three corresponding longitudinal rows of staples. Further, the two pairs of longitudinal slots extend to the end of cartridge 232.

Cam bars 278 are provided with a cam surface 304 in an upper distal end thereof and an overhanging ledge 306 with vertical surface 308 in a lower distal end. This overhanging ledge 306 is dimensioned to extend into the longitudinal slots to a point wherein the vertical surface 308 of the overhanging ledge 306 drops down and abuts the forward edge 310 of the cartridge retaining portion of the cartridge housing 260 when the cam bars 278 move to their distal fired position. At their proximal end, cam bars 278 are provided with hook structure 312 for releasably engaging cam bar adaptor 280.

Referring now to Figs. 22-24, there are shown multiple views of the cam bar adaptor 280. The cam bar adaptor 280 comprises a forward section 314 and a rearward section 316. The forward section 314 is substantially rectangular in shape and has a central longitudinal groove 318 formed therein and dimensioned to receive the longitudinal groove structure 302 therein when the cam bar adaptor is urged to its forwardmost position. Flanges 320 and shelves 322 serve to removably retain the proximal end of cam bars 278.

The rearward section 316 is rectangular in shape with projections 324 formed in the proximal end thereof. The rearward section is dimensioned to be receivable within the slot formed in fork 194 in channel 192. The projections 324 are dimensioned to engage ramping surface 198 to allow the fork 194 to ride up and over the projections 324 when the fork 194 is moved in the distal direction.

Vertical bore 326 and longitudinal groove 328 are formed in the rearward section 316 and serve to retain and hold the shank of knife 254. Shear pin 294 is integrally formed with cam bar adaptor 280 on a bottom surface thereof and, in the prefiring position, is aligned with and receivable into bore 292. Also, in this prefiring position, the rearward

section 316 of the cam bar adaptor 280 is disposed over rearward projection 290 to effectively shield engagement of abutting structure 202 with projection 290.

Turning now to Figs. 28-34, there is shown a second anvil and cartridge assembly. Referring to Figs. 28 and 29, the cartridge assembly 330 comprises a cartridge housing 332 mounting a cartridge 334 containing a plurality of pushers 336 disposed beneath staples 338, in a distal end thereof. A pair of cam bars 340 are positioned in the cartridge housing 332 and are adapted to move longitudinally through parallel longitudinal slots formed in cartridge 334. A camming surface 342 is formed on an upper distal end of cam bars 340 with an overhanging ledge 344 formed on a lower distal end. Vertical ledge 346 is formed proximal to overhanging ledge 344 and is adapted to engage the distal end of cartridge housing 332 when the cam bars 340 are driven to their full distal position. A cam bar alignment tab 348 engages both cam bars 340 and holds them in parallel alignment. A cam bar adaptor 350 is adapted to fixedly receive the shank portion of cam bars 340. Cartridge 334 is designed with three longitudinal rows of staples with each row of staples being offset from adjacent rows as shown in Fig. 28.

Referring to Figs. 30-31, an anvil 352 is shown having substantially the same design as anvil 230 described hereinabove. The primary difference is that the distal portion 354 of anvil 352 is narrowed to receive and form three longitudinal rows of staples in contrast to the six rows of staples and knife accommodated by anvil 230. Anvil 352 includes a pair of longitudinally extending parallel legs 356 having transverse opposing projections 358. Parallel aligning surfaces 360 are formed in sidewalls of anvil 352 and serve to overfit and align anvil 352 on cartridge housing 332. First and second camming surfaces 362, 364 are formed in sidewalls of anvil 352 proximal to parallel aligning surfaces 360 and serve to engage camming bosses 268, 270 formed in forward collar tube 222 and rear collar tube 224, respectively.

Upper camming surface 366 is formed on an upper surface of anvil 352 proximal to distal end 354 with locking surface 368 formed distally adjacent upper camming surface 366. Both the upper camming surface 366 and the locking surface 368 are adapted to engage and be cammed by top arcuate camming surface 246 formed in the distal end of forward collar tube 222.

Figs. 35-39 show a further surgical instrument similar to that shown in Figs. 1-15 with the jaw structure of Figs. 28-34. Referring to Figs. 35-36, the handle portion of this embodiment further includes annular seals 101, 103 provided between the distal end of frame 52 and the proximal end of

cover tube 182. These seals serve to further inhibit the escape of insufflation gas from the operative site. Seals 107 and 109 are positioned adjacent the proximal and distal ends, respectively, of clamp tube 70 to better seal off insufflation gas from the area of the piston 104.

A counter mechanism is also disposed in handle portion 52 and comprises a counter ratchet 400 attached to trigger rod 112 and a leaf spring 402 mounted in housing 66 so as to engage the teeth on the bottom surface of counter ratchet 400. Numerical indicators are longitudinally disposed on an outer surface of the counter ratchet 400 and correspond to the number of times the instrument has been fired. An access plate 404 having a viewing window 406 therein is positioned in the outside surface of housing 66.

In operation, each time the instrument is fired the leaf spring 402 engages a respective proximally located tooth of the counter ratchet 400, effectively sliding the counter ratchet 400 distally to align the next lower number in viewing window 406. The counter mechanism of this embodiment further includes a locking feature whereby the trigger button 96 is retained in the fired position when the leaf spring 402 engages the most proximal surface of the counter ratchet 400 and prevents the firing rod 112 from returning to its proximal unfired position.

This instrument further includes an integral trigger button rotary safety mechanism comprising a rotary safety shaft 408 disposed within a roller 410. The rotary safety mechanism is rotatably positioned in trigger button 96 with the roller 410 extending out beyond the plane of the back surface of trigger button 96. Projections 412 are eccentrically formed on both sides of rotary safety shaft 408 and extend out beyond the plane of the side surfaces of the trigger button 96. Spring 414 serves to normally bias the rotary safety mechanism with the projections 412 disposed in their distalmost orientation.

Referring now to Figs. 38 and 39, in the instrument's unfired position (Fig. 38) projections 412 are in their distalmost position and are disposed in direct alignment with the proximal ends of the housing members 64, 66. In this position, the trigger button 96 cannot be accidentally depressed to fire the instrument. In order to disengage the safety mechanism, the roller 410 is moved in the direction of arrow 416 which serves to rotate projections 412 from their distalmost position (Fig. 38) to their proximalmost position (Fig. 39) effectively allowing trigger button 96 to be depressed to fire the instrument. As soon as roller 410 is released, spring 414 returns the safety mechanism to its normal position to prevent subsequent accidental firings.

Fig. 37 shows the endoscopic portion and the jaw portion of the surgical apparatus of Fig. 35. The

anvil 418 of this embodiment is provided with a pair of angled proximal legs 420. This feature permits the anvil 418 to be opened wider to more easily receive tissue between the anvil 418 and cartridge 58. The angled proximal legs 420 preferably extend at an angle of between 0 and 30° from the longitudinal plane of the anvil.

A clamp lockout structure is shown in detail in Figs. 37, 40 and 41 incorporated into the support structure 214 and upper extension spacer 210. The clamp lockout structure comprises a leaf spring 430 having a diagonally downwardly extending projection 432 attached thereto. A slot 434 is formed through the top surface of support structure 214 and is adapted to engage and receive projection 432 whenever the support structure is not longitudinally aligned. This clamp lockout structure is designed and configured to prevent the instrument jaws from closing on tissue unless the cartridge and/or jaw elements are properly emplaced within the apparatus.

In operation in the stapling apparatus of Fig. 37, leaf spring 430 and projection 432 are normally disposed above support structure 214. The proximal ends of the cartridge 334 and the anvil 418 are inserted through collar tube 222 and brought into engagement with the distal end of support structure 214. (See Fig. 40) In the event that the cartridge 334 and/or the anvil 418 are not properly and/or completely inserted into engagement with support structure 214, the resulting angular disposition of the support structure 214 brings slot 434 into alignment with projection 432. (See Fig. 41) As the operator attempts to depress the handle 62, the extension spacer 210 begins to move distally causing projection 432 to enter slot 434 and become entrapped therein effectively preventing any further distal movement of the extension spacer 210 and, in turn, preventing approximation of the anvil 418 and the cartridge 334.

In use, the endoscopic portion of the instrument is inserted into the body, preferably through an endoscopic tube. It is further preferred that the endoscopic tube apparatus be capable of maintaining a sealed pneumoperitoneum, with the internal sealing member of the housing further maintaining this seal despite introduction of the instrument in accordance with the invention into the endoscopic tube. As a practical matter, the jaws of the instrument are closed for insertion into the endoscopic tube, either by pinching the anvil and cartridge prior to insertion or by closing the articulating handle to cam the jaws closed prior to insertion.

After insertion into the endoscopic tube, the endoscopic portion may be rotated in order to appropriately orient the instrument at the stapling site. Rotation of the endoscopic portion relative to the body may be attained by rotating the instru-

ment, as a whole, by rotating the endoscopic portion relative to the frame using rotation knob 228 (See Fig. 1), or by a combination thereof.

Referring to Figs. 3, 5-8 and 32-34, with the instrument properly oriented so that the tissue to be fastened is disposed between the open jaws of the instrument, i.e., between the tissue contacting surfaces of anvil member 230 and cartridge 302, the jaws are closed to clamp the tissue. In the first embodiment, the surgeon presses down on actuating handle 62, thereby sliding collar tube assembly 220 distally, via clamp tube 70, extension sleeve 204, and extension spacers 210, 212.

Referring to Figs. 32-34, as collar tube assembly 220 moves distally in the direction of arrow A from a first position where the top arcuate camming surface 246 at the distal end of forward collar tube 222 is proximal to camming surface 242, (Figs. 32-33), to a second position where the top arcuate camming surface 246 is engaged with locking surface 244, (Fig. 34), the top arcuate camming surface 246 contacts the camming surface of the anvil, thereby forcing the anvil to cam via camming surfaces 264, 266 on camming bosses 268, 270 until the anvil is brought into close cooperative alignment with the cartridge assembly. Fig. 34 illustrates the instrument with the jaws in a closed position.

After closing the instrument jaws, the instrument is ready to be fired. When the surgeon is ready to emplace the staples and cut tissue, firing trigger 96 is depressed to actuate the pneumatic actuator 98 as discussed in detail above. Piston 104, attached to the proximal end of channel 192 is driven distally causing camming surface of forks 194 to ride up and over projection 324 of the cam bar adaptor 280 and drive the cam bar adaptor in a distal direction. Shear pin 294 is severed and the cam bars and knife are driven longitudinally through the cartridge to sequentially drive and form staples and cut tissue.

As piston 104 contacts return springs 140, 142, pusher washers 186 are compressed on themselves and serve to store energy as the piston moves distally toward the cartridge assembly. This initial compression occurs in the range of between about 20 p.s.i. to about 150 p.s.i. and preferably within a range of about 30 p.s.i. to about 60 p.s.i. Near the end of the distal stroke of the piston 104, this stored energy is released to drive the cam bars 278 through the final distal limits of their travel within the longitudinal slots in the cartridge. At the distal extreme of the longitudinal stroke, the overhanging ledges 306 of cam bars 278 drop over the edge of the cartridge housing thus abutting vertical surface 308 with edge 310.

After firing, return springs 140, 142 engage piston 104 and return it to its original position. The

return motion of piston 104 causes rocking lever 120 to be cammed aside by camming surface 144 of piston 104. In the embodiment containing knife 254 discussed above, the cam bars 278 are pulled out of cam bar adaptor 280 and remain in position in the longitudinal slots of the cartridge 334. The cam bar adaptor, with knife 254 attached, moves proximally within cartridge housing 272 until the outer edges of cam bar adaptor 280 impinge on crimps 296.

The cam bar adaptor 280 is held in place by crimps 296 while camming surface 200 of fork 194 causes the fork to ride up and disengage with projection 324 of the cam bar adaptor. Channel 192 continues to move in the proximal direction until abutting structure 202 is positioned proximally to rearward projection 290 formed in the floor of cartridge housing 260. At this point, the entire cartridge assembly 232 is deactivated.

In the event that the surgeon should accidentally attempt to again fire the instrument without replacing the deactivated cartridge with a new unfired cartridge, the resulting distal longitudinal motion of the channel 192 moves abutting structure 202 into contact with rearward projection 290 effectively preventing further movement of forks 194 toward cam bar adaptor 280.

After firing, articulating handle 62 is raised with the assistance of handle return spring 82 which action retracts collar tube assembly 220. This retraction causes anvil 230 to cam out of engagement with cartridge assembly 232. Similarly, raising of articulating handle 62 causes cam slide 124 to move upward disengaging the pneumatic firing mechanism.

In order to replace the cartridge assembly, the instrument is withdrawn from the patient. The cartridge assembly is released and may be removed by pulling it distally out of collar tube assembly 222.

To reinsert a new cartridge assembly, the proximal end of the cartridge assembly is inserted into collar tube assembly 222 until engaging and locking into support structure 214. The instrument is now ready for reinsertion and continued use.

Operation of the instrument with the cartridge and anvil assembly shown in Figs. 28-31 is substantially similar to that described above. Tubular tissue to be ligated and/or divided is captured within the anvil 352 and the cartridge assembly 330 such that the tissue is transversely oriented therebetween. The cartridge assembly 330 and anvil 352 are approximated by means of camming surfaces 362, 364 and camming bosses 268, 270, as described above. The staples 338 are fired, ligating the tissue.

Unlike the instrument described previously, the cartridge assembly 330 does not include a knife

and therefore does not require that the cam bars be retracted by channel 192. In operation, the distal end of channel 192 engages the proximal end of cam bar adaptor 350 and drives cam bars 340 to their extreme distal position (Fig. 34). In that position, overhanging ledges 344 drop over the distal end of cartridge housing 332 and remain there. As the piston 104 retracts, channel 192 moves away from cam bar adaptor 350 and retracts to a position proximal to rearward project 290, this leaving cam bars 340 and cam bar retainer 350 in the distal position within cartridge assembly 332. Opening, removal and replacement of the deactivated cartridge are effected in substantially the same way as described above with respect to the second alternative embodiment.

Referring to Figs. 42-45, there is illustrated a unique counter mechanism which is designated generally by reference numeral 450. Counter mechanism 450 is operatively associated with actuation trigger 96 and is configured to visually indicate to the user the number of times the surgical apparatus of the subject invention may be fired, and to prevent the operation of the pneumatic actuation system 68 after a predetermined number of firings. This effectively prevents the apparatus from being fired when there may be an insufficient quantity of compressed gas contained within gas supply canister 88.

In brief, as illustrated in Fig. 42, the counter mechanism 450 of the subject invention includes a spring biased indexing shaft 452 having a ratchet tooth 454 formed at the proximal end thereof for interacting with a linear rack member 456. The indexing shaft 452 extends proximally from an indexing block 458 which is slidably mounted on a rail 460. The rail is connected to a bracket 462 which is mounted to the inner surface of housing member 66. A coiled compression spring 464 is also mounted on rail 460, distal to the indexing block 458, for biasing the indexing block 458 in a proximal direction. The indexing block 458 is dimensioned and configured to interact with piston 104 as it travels in a distal direction when the surgical apparatus is operated. In particular, a flange 104a depends outwardly from the piston 104, adjacent the piston head 104b, for contacting the indexing block 458 as the piston 104 advances toward the distal end portion of handle 62, as illustrated in Fig. 43, to index the rack member 456 to the position illustrated in Fig. 44.

With continued reference to Fig. 42, the rack member 456 includes an upper set of five ramped engagement notches 466a-466e and a lower set of five corresponding ramped engagement notches 468a-468e. The ratchet tooth 454 interacts with the upper set of engagement notches to incrementally advance the rack member 456 each time the ap-

paratus is fired, and a leaf spring 470 interacts with the lower set of engagement notches of rack member 456 for sequentially maintaining the rack member 456 in an incrementally indexed position.

Numerical indicia are imprinted on the outside surface of rack member 456 and are sequentially visible through a windowed porthole 472 provided in the side wall of handle 62. The numerical indicia correspond to the five engagement notches 466a-466e defined on rack member 456. In particular, notches 466a-466e correspond to the numerals "4-0", respectively. Each numeral identifies the number of times the pneumatic actuation system 68 may be actuated to operate the surgical apparatus of the subject invention. One skilled in the art will readily appreciate that, depending upon the volume of gas needed for actuation, and/or the volume of the supply container, the number of engagement notches formed on rack member 456 can be increased or decreased.

Rack member 456 is dimensioned and configured to interact with the trigger rod 112 which extends from the trigger 96. More particularly, a blocking tab 112a depends outwardly from the trigger rod 112. The blocking tab 112a is dimensioned and configured for engagement within a corresponding reception notch 474 formed in housing 66 of the surgical apparatus. In use, when the apparatus is fired for the fourth and final time, the indexing shaft 452 will index the rack member 456 to the distal-most position illustrated in Fig. 45. At such a time, the rack member 456 will urge the blocking tab 112a into the reception notch 474. As a result, the trigger rod 112 will be maintained in a distal position and, as a consequence, further user actuation of trigger 96 will be inhibited.

In another embodiment of the subject invention which is illustrated in Figs. 46 and 47, there is provided a modified lockout mechanism which prevents the instrument from being fired unless an unfired cartridge assembly has been correctly inserted into the instrument. Specifically, a channel stop 480 is affixed to an underside of channel member 192, preferably by welding or, alternatively, may be integrally formed in channel member 192. A lower extension sleeve return stop 482 is affixed to lower extension spacer 212 and is configured and dimensioned, as described hereinbelow, to interact with channel stop 480.

Upon loading a cartridge assembly, such as cartridge assembly 60, for example, opposed ramping surfaces 198 and 200 on forks 194 of channel member 192 ride up and over the angled face 484 of cam bar adaptor 280 (Fig. 46). After the instrument has been fired, channel member 192 returns with piston 104 in a proximal direction to disengage from cam bar adaptor 280. As shown specifically in Fig. 47, as channel member 192 returns proximally,

channel stop 480 abuts lower extension sleeve return stop 482, thereby preventing the complete return of piston 104 and channel member 192 to an original prefired position.

Referring now to Figs. 48 and 49, the trigger rod 112 of this embodiment is structurally modified to include a distally facing projection 112b and a modified rocking lever 486. The rocking lever 486 includes an arcuate groove 488 at a lower end portion thereof for engagement with a rocking lever stop 490, as shown in Fig. 48, which is affixed to an inside surface of housing member 66.

As noted above with respect to the previously described embodiments of the invention, in operation, when trigger 96 is pushed distally, trigger rod 112 translates distally to engage transverse projection 120 on piston slide 114 of piston 104. As piston slide 114 is driven forward, it pivots the modified rocking lever 486, which, in turn, actuates the pneumatic actuation system 68 to drive piston 104 forward to eject staples from the cartridge assembly 60.

As piston 104 advances in a distal direction, the top surface of the modified rocking lever 486 rides beneath piston 104. As shown, for example in Figs. 5 and 7, when piston 104, has been fully fired, the modified rocker lever 486 enters a gap 138 in piston 104, allowing rocking lever 486 to pivot back to stop the flow of gas from cylinder 88. Initially, when piston 104 begins to return proximally, a camming surface 144 in gap 148 biases rocker lever 486 transversely, against the bias of spring 144. As piston 104 continues to return in a proximal direction, rocking lever 486 rides along a side edge of piston 104. In the embodiments described hereinabove, in a return stroke, the piston 104 would fully return to a point where the piston slide 114 would be disposed proximal of rocking lever 486, permitting the rocking lever 486 to translate rearwardly against the bias of spring 144. However, in the present embodiment of the subject invention, piston 104 is prevented from fully returning since lower extension sleeve return stop 482 engages the channel stop 480 on channel member 192 preventing the full return of piston 104.

As shown in Fig. 48, rocking lever 486 is maintained in a laterally displaced position compressing spring 144 transversely. In this position rocking lever 486 engages rocking lever stop 490 and is prevented from pivoting. Should the user attempt to depress the trigger 96, projection 112b on trigger rod 112 will abut the modified rocking lever 486. Since projection 112b abuts the modified rocking lever 486, upon depression of trigger 96, the distal end of trigger rod 112 is prevented from advancing distally and cannot engage the transverse projection 120 of piston slide 114. In this manner, the trigger mechanism is "locked out" and

disabled from firing. Once a new fully loaded cartridge assembly has been inserted into the instrument, the opposed ramping surfaces 198 and 200 of forks 194 on channel member 192 ride up and over the sloped faces 484 of cam member 280. As a result, channel stop 480 is lifted out of engagement with lower extension sleeve return stop 482 allowing the piston 104 to fully reset, as shown in Fig. 49.

In sum, after firing the instrument, piston 104 will be prevented from fully resetting due to the orientation of channel stop member 480, and the modified rocking lever 486 will be maintained out of alignment with the piston slide 114 and prevented from pivoting by rocking lever stop 490. In addition, projection 112b on trigger rod 112 engages or abuts modified rocking lever 486, thus preventing the distal end of trigger rod 112 from engaging transverse projection 120 on piston slide 124. As a result, the device is disabled until a new fully loaded cartridge has been inserted.

Referring to Fig. 50 in conjunction with Figs. 46 and 47, in a modification of the previously described embodiment, there is also provided a cartridge identification adaptor which comprises a transverse bridge 490 formed between forks 194 of channel member 192. Bridge 490 serves to prevent a cartridge having incompatible firing characteristics, but which would otherwise be loadable into the instrument, from firing. This is desirable to prevent firing of a cartridge having characteristics, such as, for example, length of cam bar travel, number of staples, presence or absence of a knife member, etc., in an instrument whose actuation system, i.e. gas pressure and length of piston stroke, or anvil design/layout would otherwise be incompatible. This feature, i.e., the cartridge identification feature, is equally advantageous in surgical instruments that are manually actuable as in pneumatically actuated instruments. As shown in Fig. 46, bridge 490 is dimensioned and configured to clear cam bar adaptor 280 and thereby identify a fastener cartridge compatible with the pneumatic actuation system 68 and/or anvil configuration of the subject instrument.

Referring to Fig. 50, if an unfired incompatible cartridge is loaded into the instrument, bridge 490 would engage a distal end of an incompatible cam bar adaptor 492 and drive the cam bar adaptor 492 forward into the incompatible cartridge as the cartridge is inserted. This distal movement of the adaptor 492 causes the cartridge identification structure to recognize the incompatible cartridge as a "fired" cartridge. Specifically, incompatible cam bar adaptor does not have angled projections as shown in Fig. 50. In this manner, the opposed ramping surfaces 198 and 200 on channel member 192 do not engage angled projections on the in-

compatible cam bar adaptor 492 of the incompatible cartridge. Since channel member 192 is not lifted by a cam bar adaptor, channel stop 480 remains in engagement with lower extension sleeve return stop 482. Thus, piston 104 is prevented from fully resetting and, as noted above and shown in Fig. 48, rocking lever 486 is maintained out of alignment, and trigger rod 112 is disabled from engaging piston slide 114, thereby preventing the device from firing.

Upon insertion of a compatible cartridge into the device, opposed ramping surfaces 198 and 200 on channel member 192 will ride up and over angled projections 484 (see Fig. 46) on the compatible cam bar adaptor 280, raising channel stop 480 out of engagement with lower extension sleeve return stop 482, and thereby allowing piston 104 to fully reset thus enabling the instrument to be fired. In this manner, bridge 490 serves as an identifier to identify a compatible cartridge to be fired in the instrument.

Thus, for example, cartridges which include six rows of staples and a knife intermediate the two centermost staple lines, i.e., an Endo GIA[®] staple cartridge manufactured by the present assignee, would be a compatible cartridge for an Endo GIA[®] instrument whose anvil includes six corresponding staple depressions and a knife channel. By contrast, however, an Endo TA[®] staple cartridge, also manufactured by the present assignee, which includes three staple rows and no knife blade, would be an incompatible cartridge for the Endo GIA[®] instrument.

In the first embodiment the elongated slot for allowing access to the thumbwheel may be placed alternatively in the left body portion or right body portion.

The claims which follow identify embodiments of the invention additional to those described in detail above.

Claims

1. A surgical apparatus for driving surgical fasteners comprising:
 - a) a frame portion;
 - b) an elongated body portion extending from said frame portion;
 - c) a fastener applying assembly operatively associated with a distal end portion of said body portion and including:
 - i) a cartridge member having a plurality of surgical fasteners disposed therein; and
 - ii) an anvil member mounted adjacent said cartridge member against which fasteners ejected from said cartridge member are driven;

- d) fastener ejection means actuatable from said frame portion for ejecting said plurality of surgical fasteners from said cartridge assembly;
- e) a pneumatic actuation system disposed within said frame portion and operatively associated with said fastener ejection means;
- f) a trigger operatively associated with said frame portion for actuating said pneumatic actuation system; and
- g) counter means for indicating to a user the number of times said pneumatic actuation system may be operated, said counter means being adapted and configured to inhibit the actuation of said trigger after said apparatus has been operated a predetermined number of times.
2. A surgical apparatus as recited in Claim 1, wherein said counter means comprises a linear rack member configured to translate longitudinally with respect to said frame portion, and a reciprocating indexing shaft configured to interact with said rack member to advance said rack member when said pneumatic actuation system is operated.
3. A surgical apparatus as recited in any of the preceding claims, further comprising means operatively associated with said counter means for inhibiting the operation of said pneumatic actuation system after said apparatus has been operated a predetermined number of times.
4. A surgical apparatus as recited in Claim 3, wherein said means for inhibiting the operation of a apparatus comprises a blocking tab which extends from a triggering rod and is dimensioned and configured to interact with said rack member after said apparatus has been operated a predetermined number of times.
5. A surgical apparatus for driving surgical fasteners comprising:
- a) a frame portion;
 - b) an elongated body portion extending distally from said frame portion;
 - c) a fastener applying assembly operatively associated with a distal end portion of said body portion and including:
 - i) a cartridge member having a plurality of surgical fasteners disposed therein; and
 - ii) an anvil member mounted adjacent said cartridge member against which said fasteners are driven when ejected from said cartridge member;
 - d) fastener ejection means actuatable from said frame portion for sequentially ejecting said plurality of surgical fasteners from said cartridge assembly;
 - e) a pneumatic actuation system disposed within said frame portion and operatively associated with said fastener ejection means, said pneumatic actuation system including a longitudinally translating piston member, a gas power source to drive said fastener ejection means, and a rocking lever engagable with said piston and said power source in a first position and disengaged from said piston in a second position;
 - f) a trigger mechanism rod operatively associated with said frame portion for engagement with said piston to actuate said pneumatic actuation system; and
 - g) disabling means operatively associated with said pneumatic actuation system for inhibiting the operation of said trigger mechanisms in the absence of an unfired cartridge member.
6. A surgical apparatus as recited in Claim 5, wherein said disabling means includes:
- a) stop means for preventing a full return of said piston member after said fasteners have been ejected from said cartridge; and
 - b) means for maintaining said rocking lever in said second position until said piston is fully returned.
7. A surgical apparatus as recited in Claim 6, wherein said stop means includes:
- a) stop member associated with said elongated body portion; and
 - b) a stop engaging member associated with said piston such that said stop engaging member engages said stop member after ejection of said plurality of fasteners to prevent full return of said piston to a prefired position.
8. A surgical apparatus as recited in Claim 7, wherein said stop member is a radially inward projection in said elongated body portion and said stop engaging member is a corresponding projection associated with said piston.
9. The apparatus as recited in Claim 6, 7, or 8, wherein said maintaining means includes a camming surface along one edge of said piston for camming said rocking lever into said second position and means associated with said piston for preventing said rocking lever from attaining said first position until said piston is fully returned to said prefired position.

10. The apparatus as recited in Claim 6, 7, 8 or 9, wherein said disabling means further includes blocking means associated with said trigger mechanism for preventing engagement of said trigger mechanism with said piston until said rocking lever is in said first position. 5
11. The apparatus as recited in Claim 10, wherein said blocking means includes a projection on said trigger mechanism engagable with said rocking lever when said rocking lever is in said second position, such that said trigger mechanism is blocked from engaging said piston and disengagable from said rocking lever when said rocking lever is in said first position. 10 15
12. A surgical apparatus for driving surgical fasteners comprising:
- a) a frame portion;
 - b) an elongated body portion extending distally from said frame portion; c) a fastener applying assembly operatively associated with a distal end portion of said body portion and including: 20
 - i) a cartridge member having a plurality of surgical fasteners disposed therein; and
 - ii) an anvil member mounted adjacent said cartridge member against which said fasteners are driven when ejected from said cartridge member; 25
 - d) fastener ejection means actuatable from said frame portion for sequentially ejecting said plurality of surgical fasteners from said cartridge assembly; and
 - e) identification means associated with said fastener ejection means for preventing actuation thereof when an incompatible cartridge member is inserted within said distal end portion of said body portion. 30 35 40
13. The apparatus as recited in Claim 12, wherein said identification means comprises a bridge member associated with said fastener ejection means adapted to disable said cartridge member. 45
14. The apparatus as recited in Claim 13, wherein said fastener ejection means comprises a channel and said bridge is formed on said channel. 50
15. The apparatus as recited in Claim 12, 13 or 14, wherein said incompatible cartridge does not include ramping structure which is present on a compatible cartridge member. 55
16. A surgical apparatus for driving surgical fasteners comprising:
- a) a frame portion;
 - b) an elongated body portion extending distally from said frame portion;
 - c) a fastener applying assembly operatively associated with a distal end portion of said body portion and including: 5
 - i) a cartridge member having a plurality of surgical fasteners disposed therein; and
 - ii) an anvil member mounted adjacent said cartridge member against which said fasteners are driven when ejected from said cartridge member;
 - d) fastener ejection means actuatable from said frame portion for sequentially ejecting said plurality of surgical fasteners from said cartridge assembly; and
 - e) stop means for preventing full return of said fastener ejection means after said fasteners have been ejected from said cartridge member. 10 15 20 25
17. A surgical apparatus as recited in Claim 16, wherein said stop means includes:
- a) stop member associated with said elongated body portion; and
 - b) a stop engaging member associated with fastener ejection means such that said stop engaging member engages said stop member after ejection of said plurality of fasteners to prevent full return of said fastener ejection means to a prefired position. 30 35 40
18. A surgical apparatus as recited in Claim 16 or 17, wherein said stop member is a radially inward projection in said elongated body portion and said stop engaging member is a corresponding projection associated with said fastener ejection means. 45 50 55

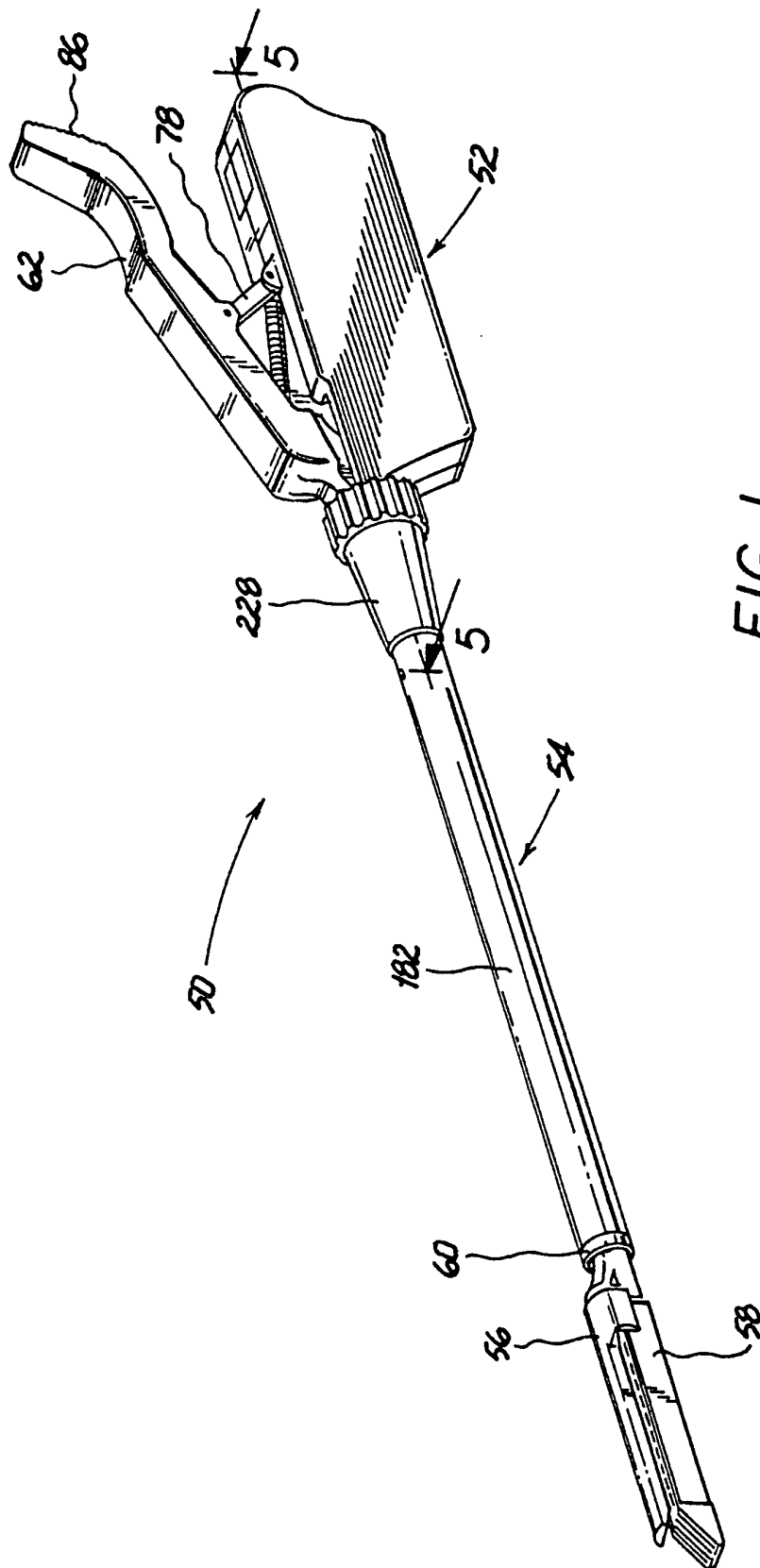
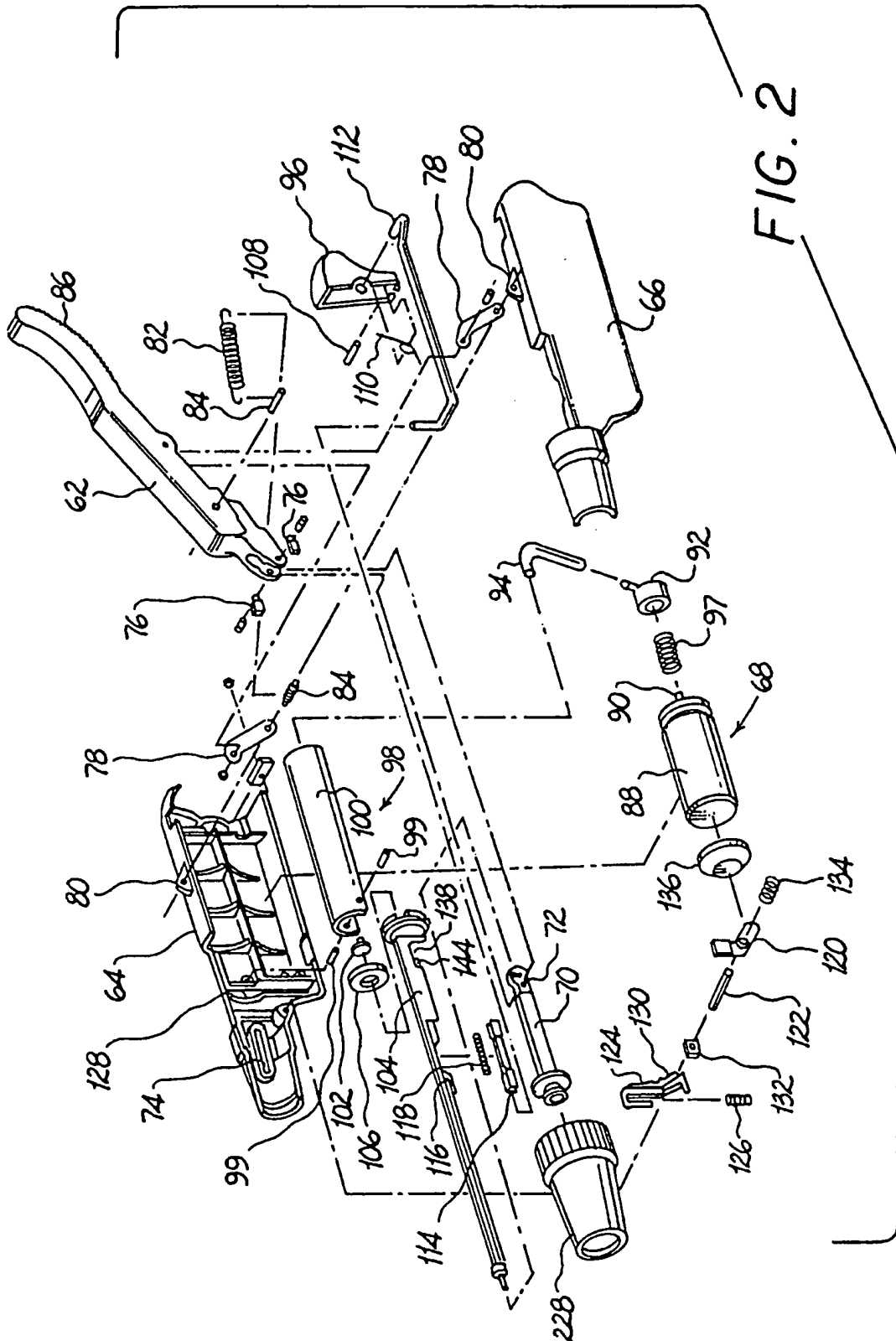
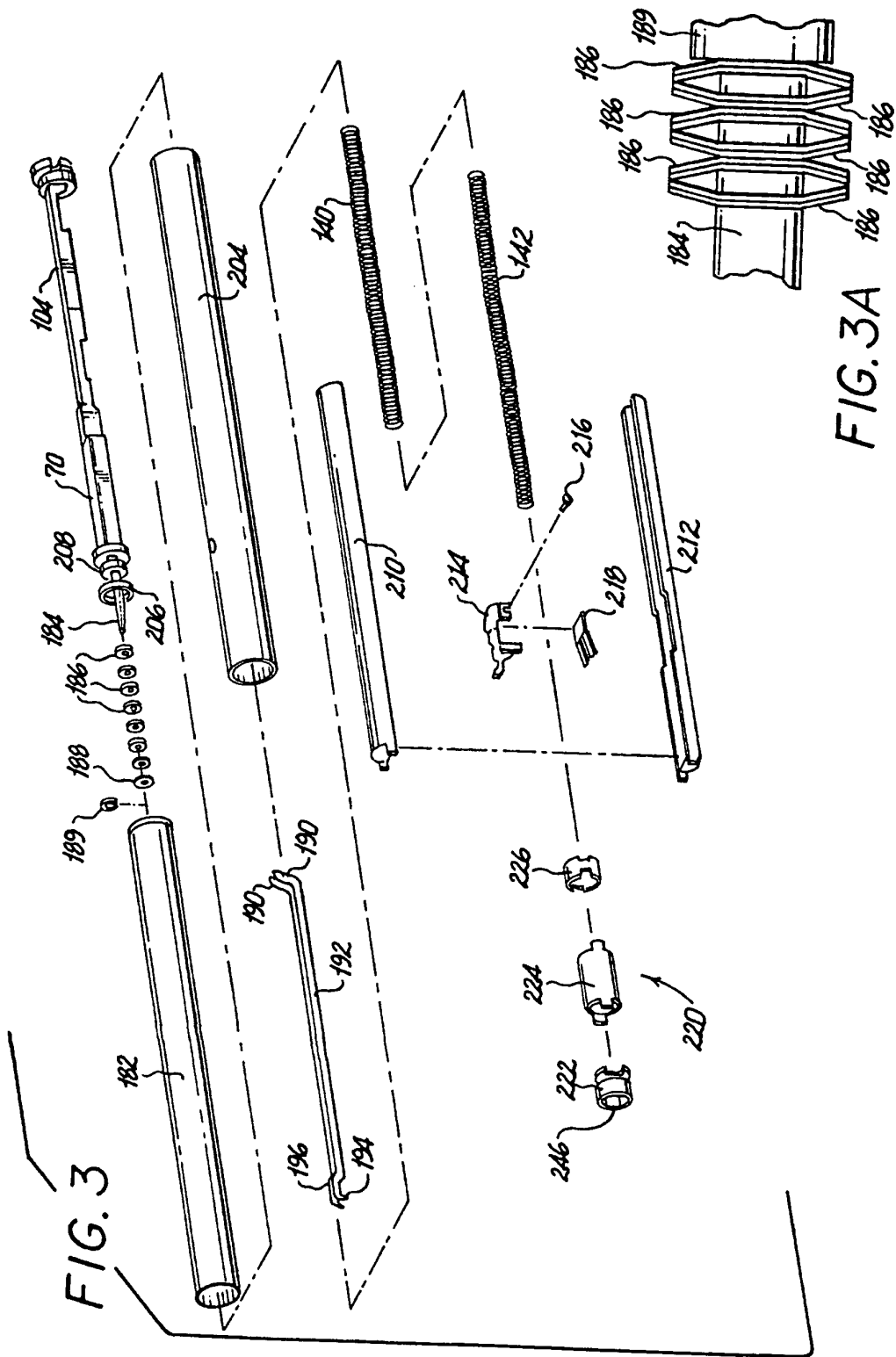


FIG. 1





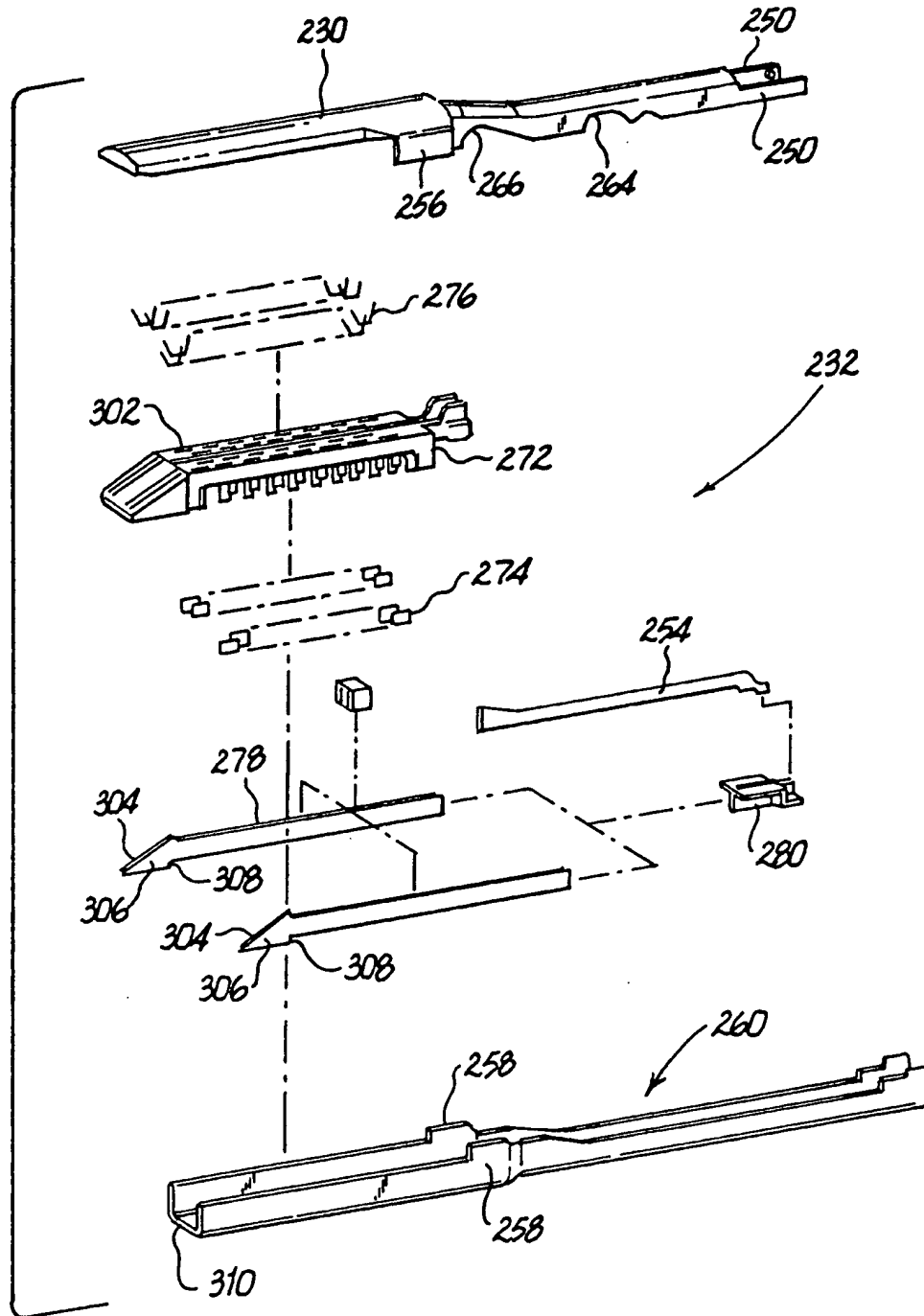


FIG. 4

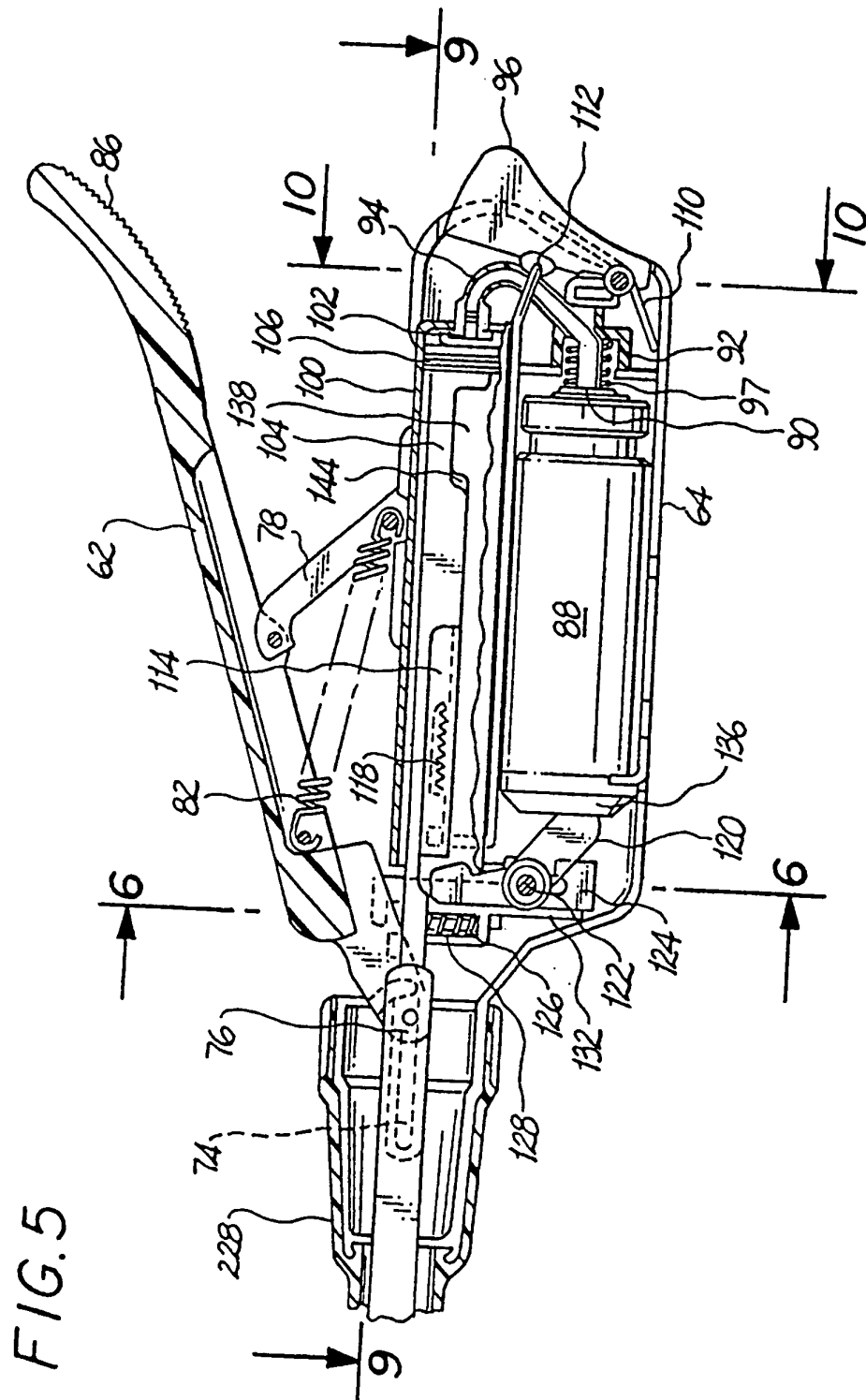


FIG. 8

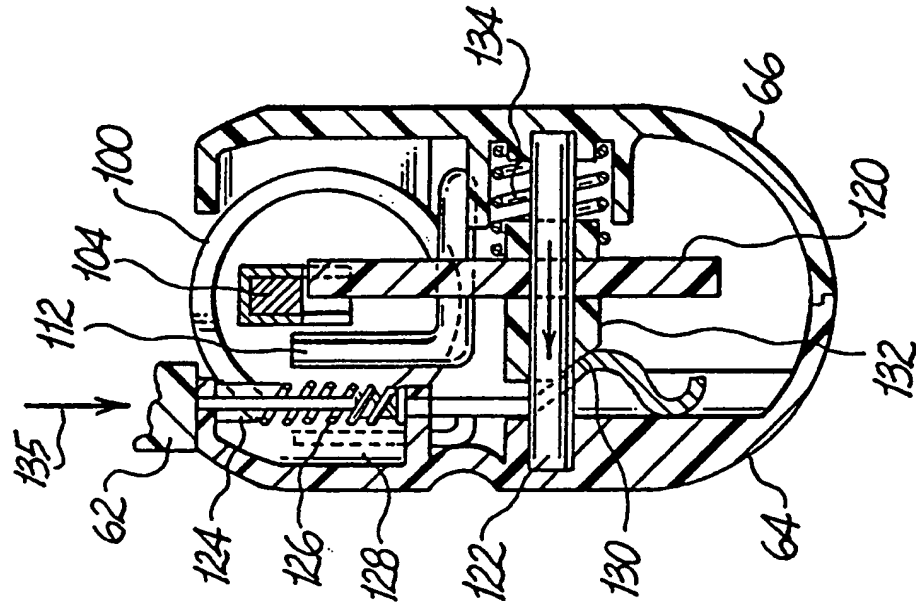


FIG. 6

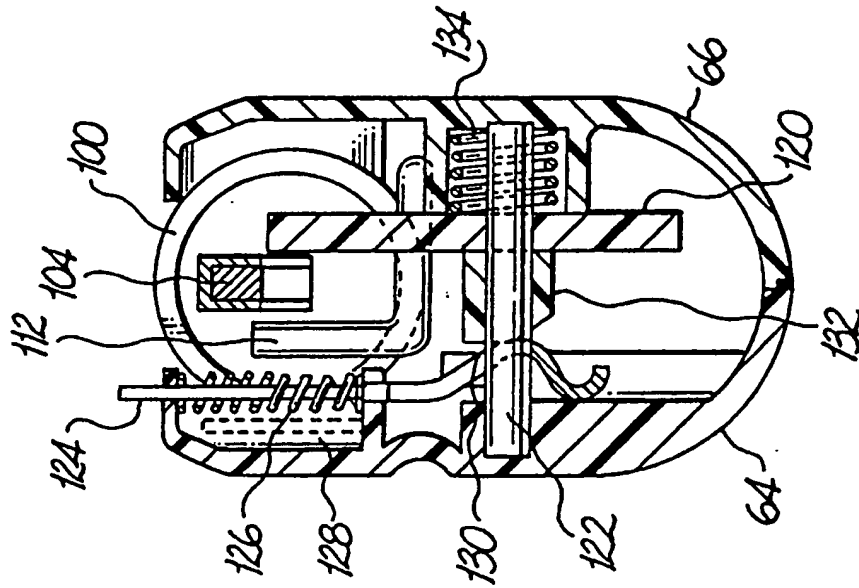
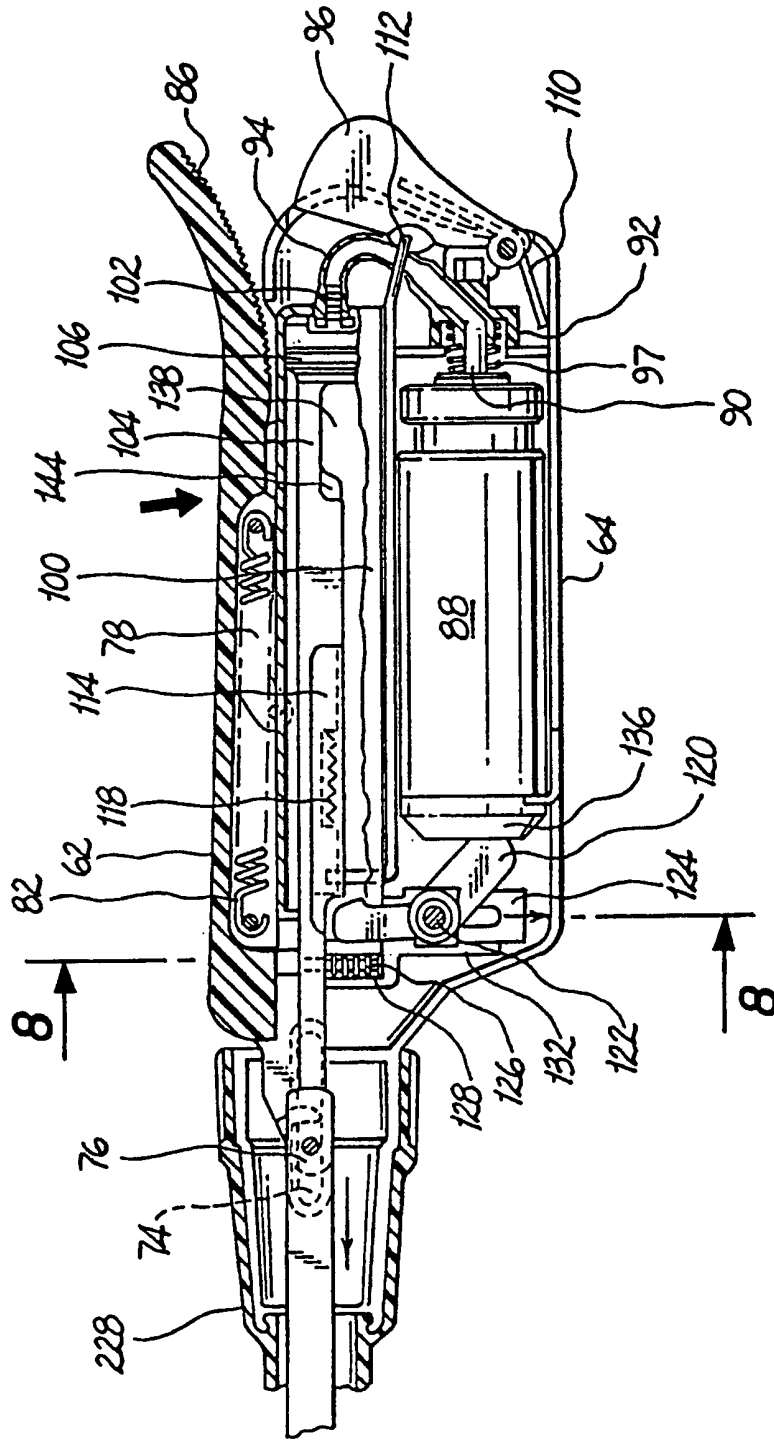
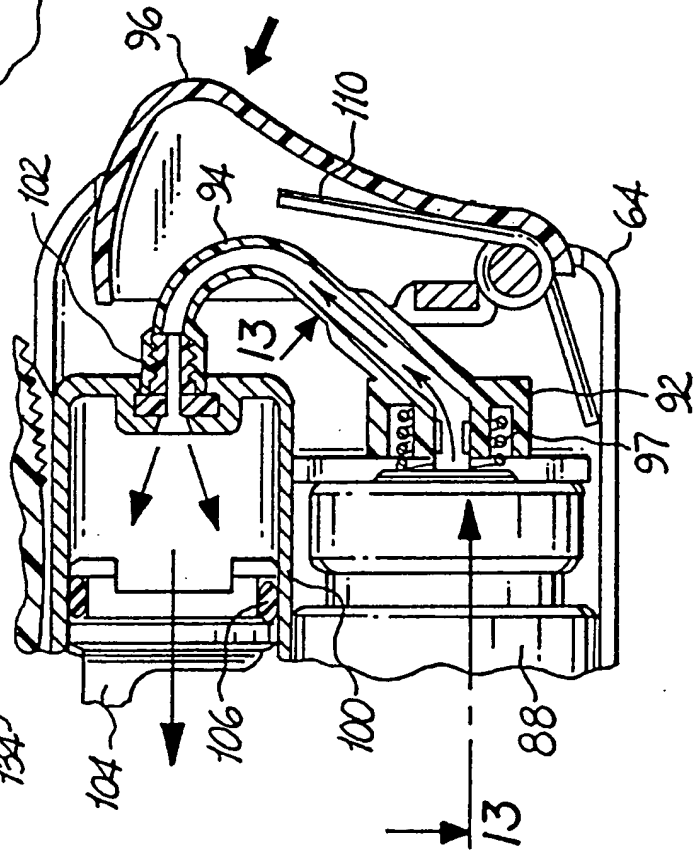
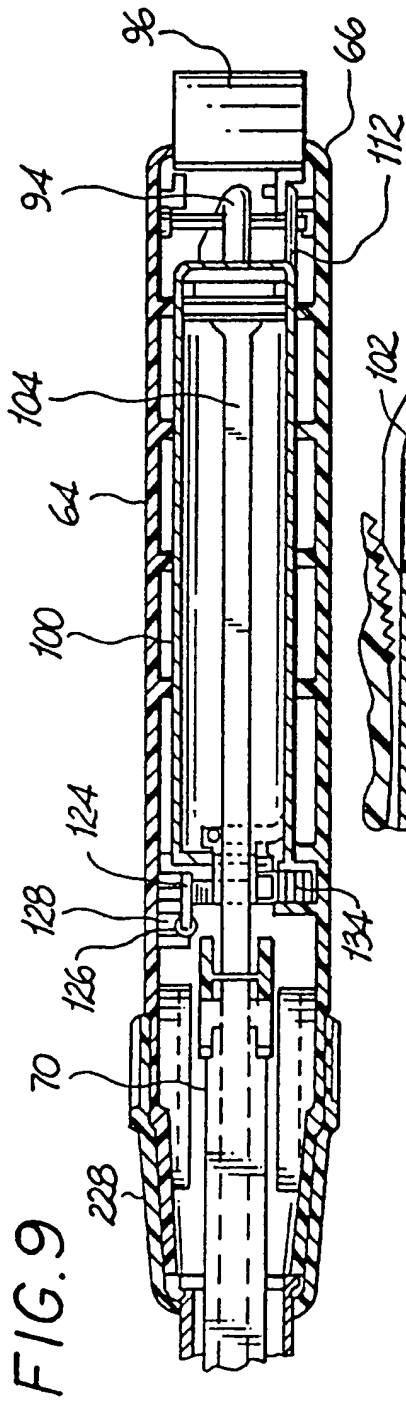


FIG. 7





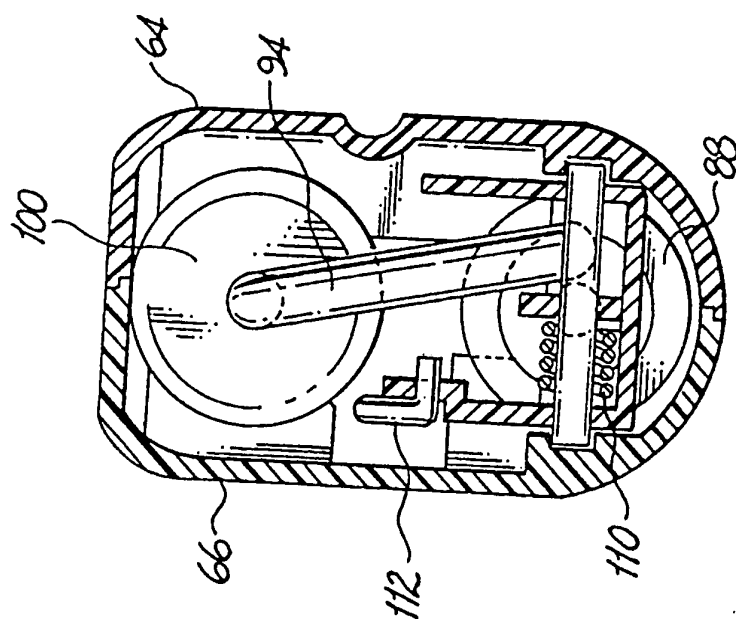


FIG. 10

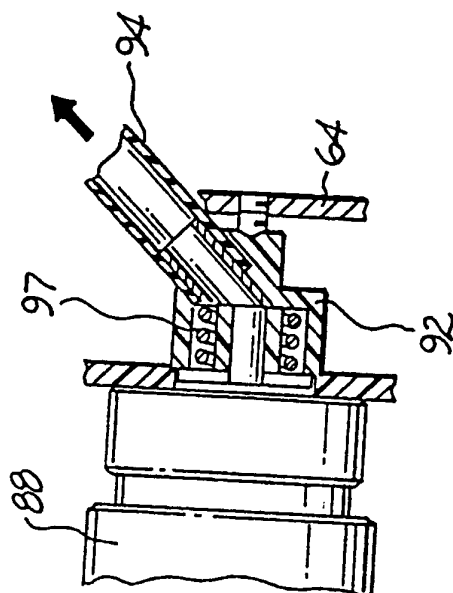


FIG. 13

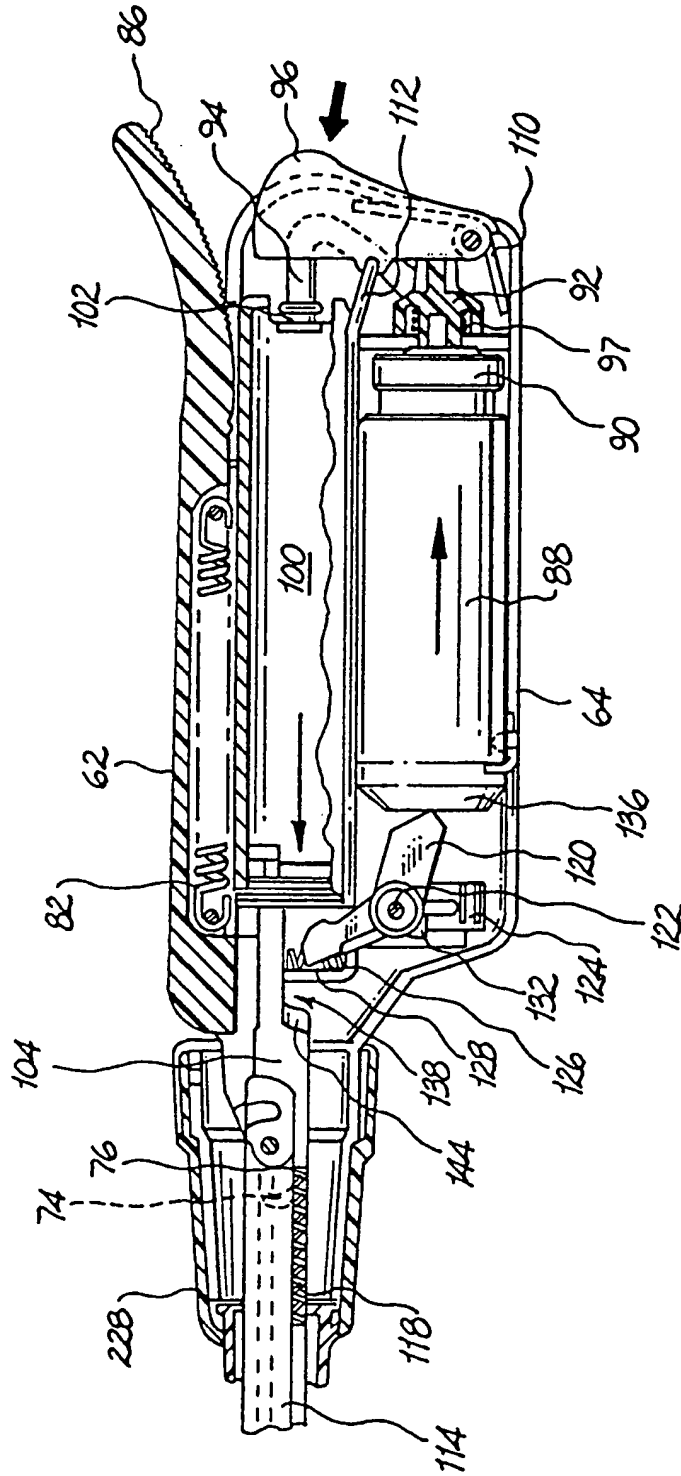
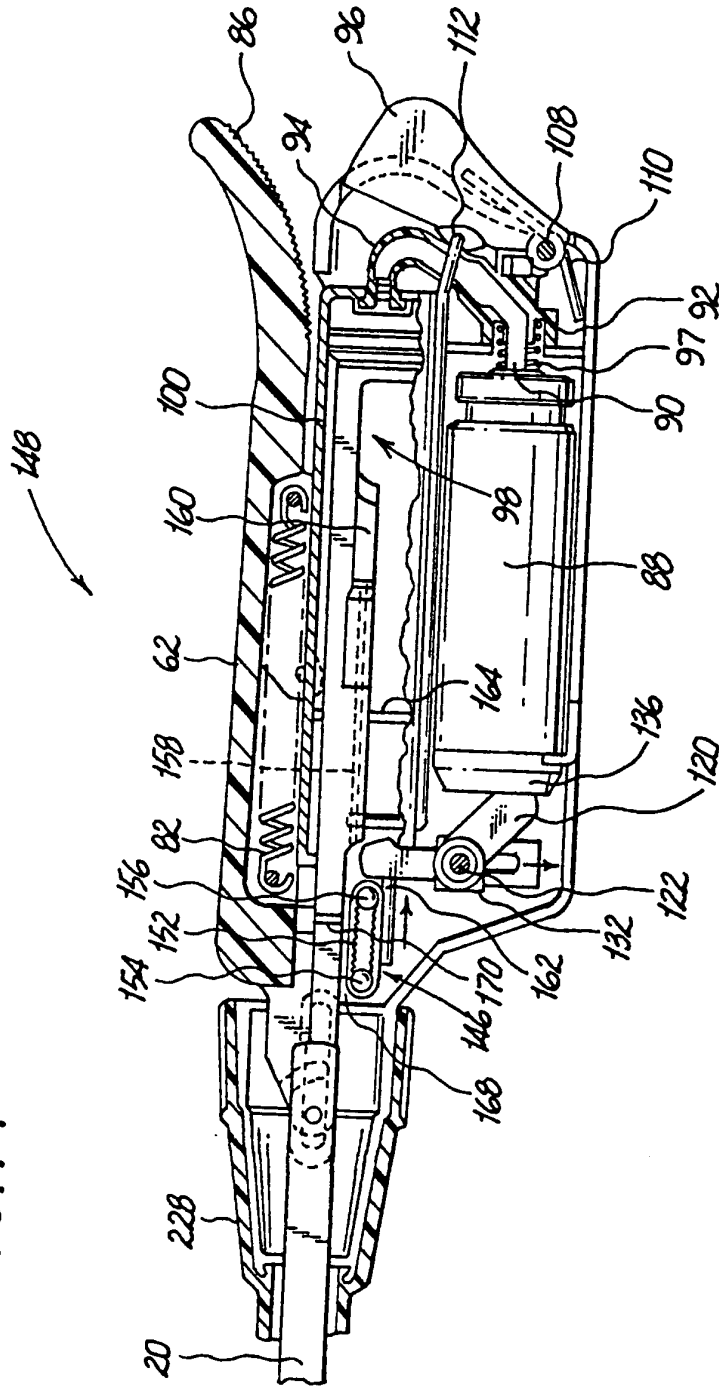


FIG. 11

FIG. 14



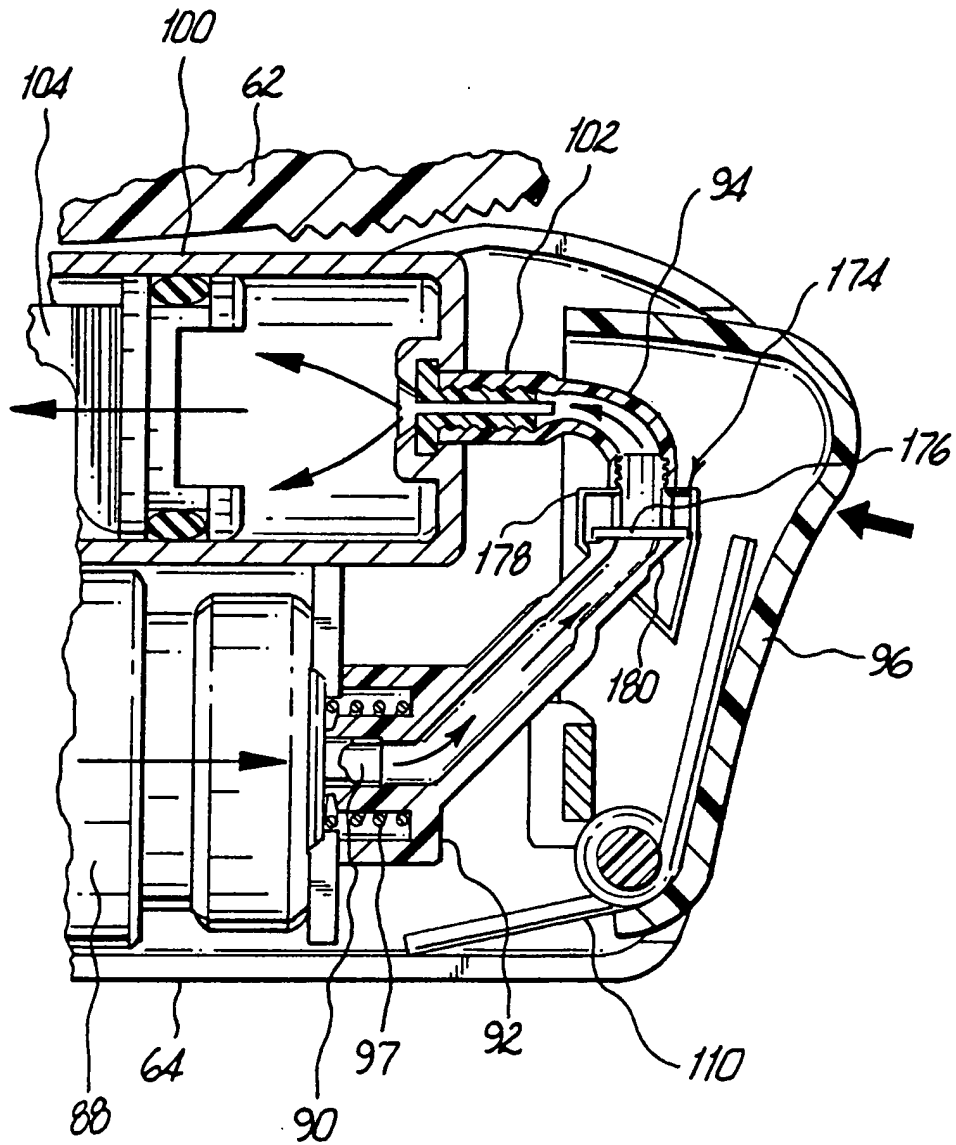
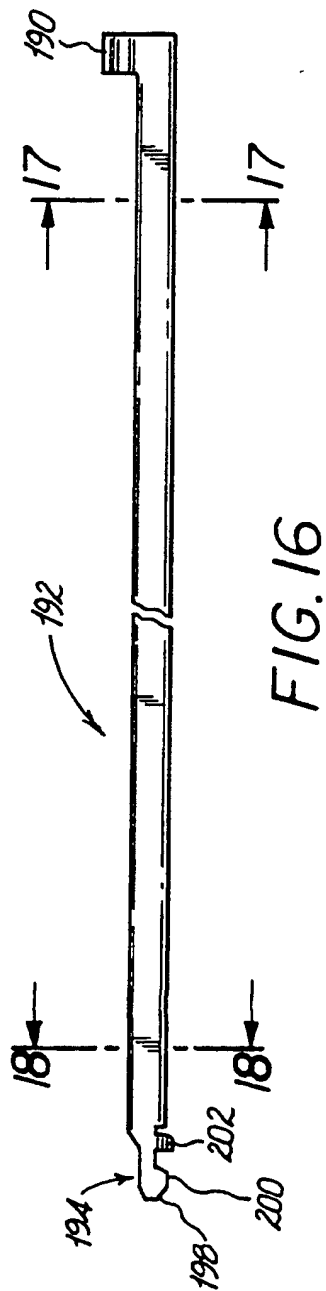


FIG. 15



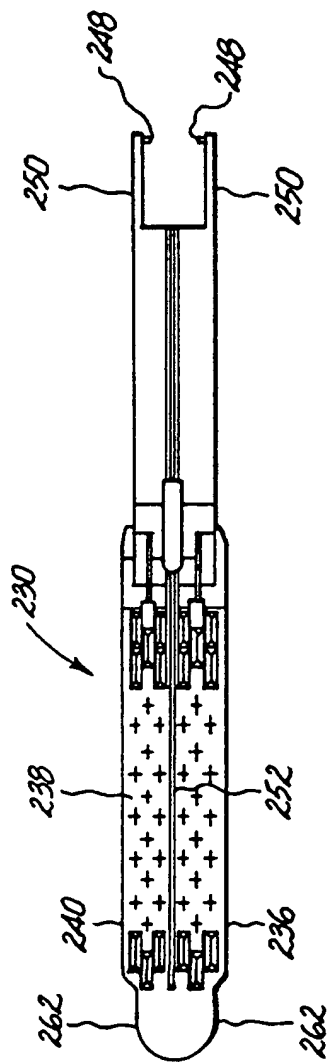


FIG. 19

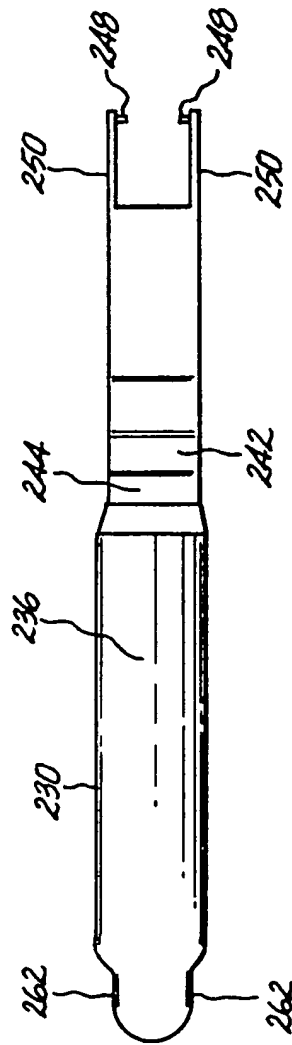


FIG. 20

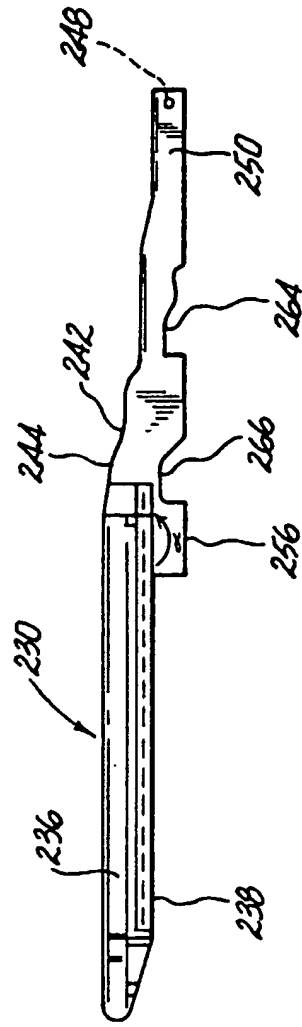


FIG. 21

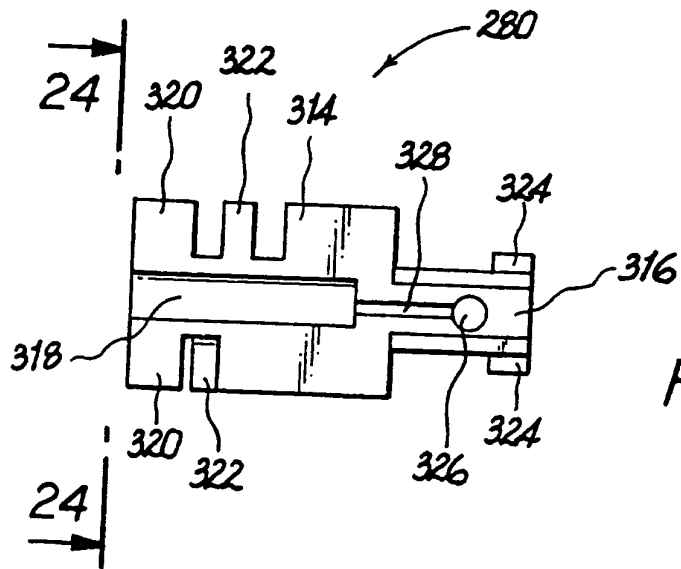


FIG. 22

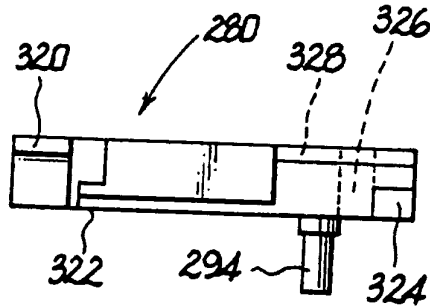


FIG. 23

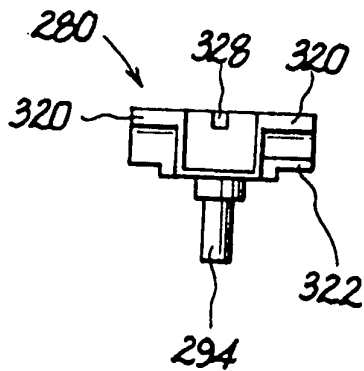


FIG. 24

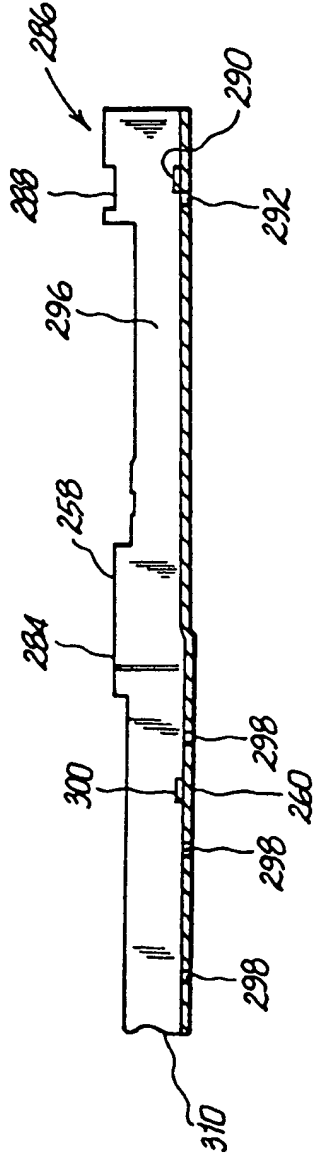


FIG. 25

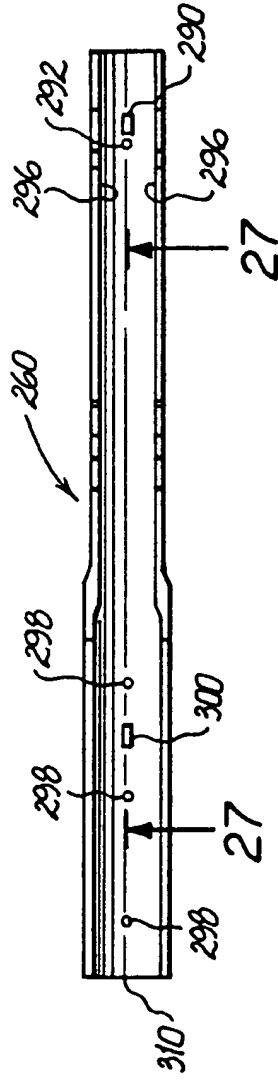


FIG. 26

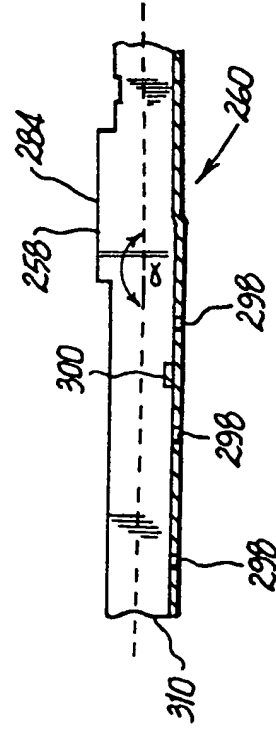


FIG. 27

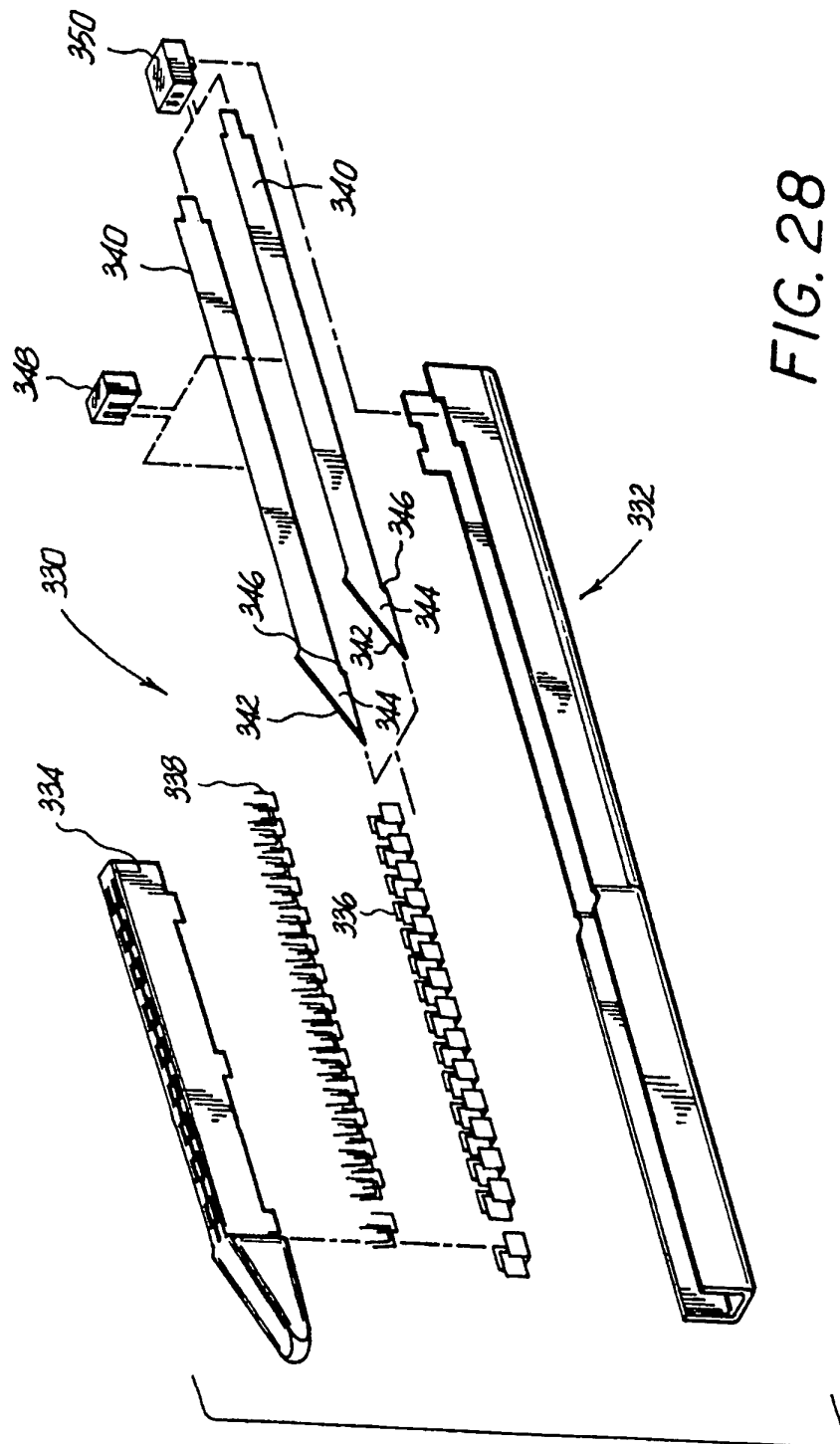
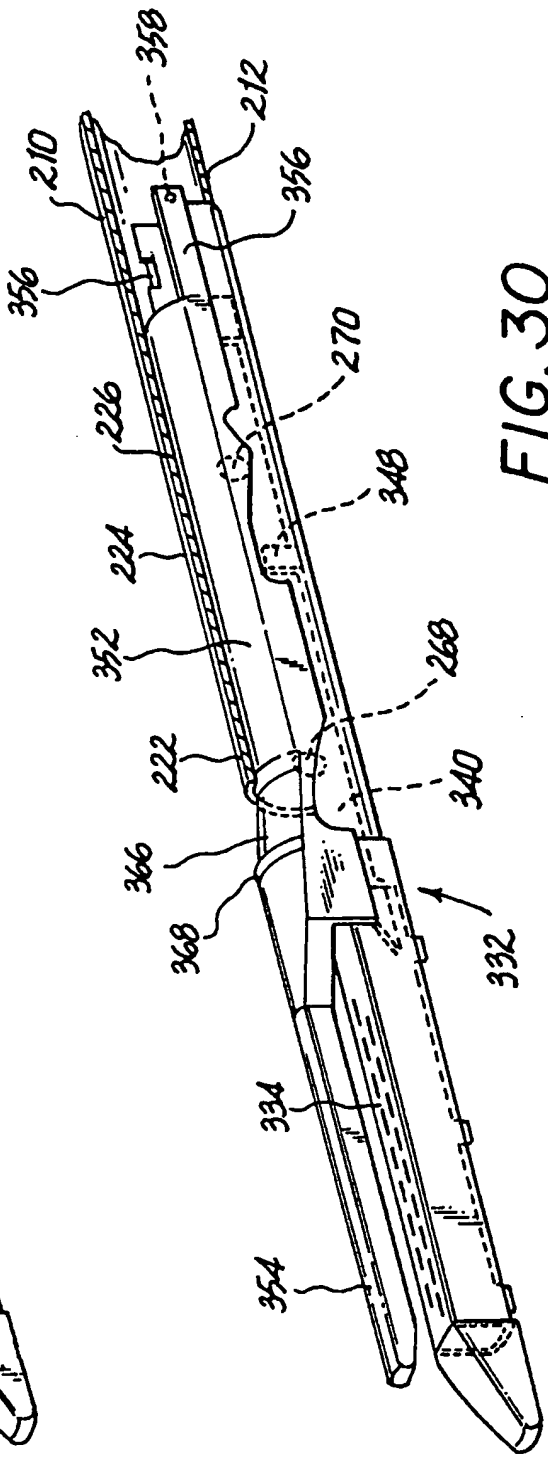
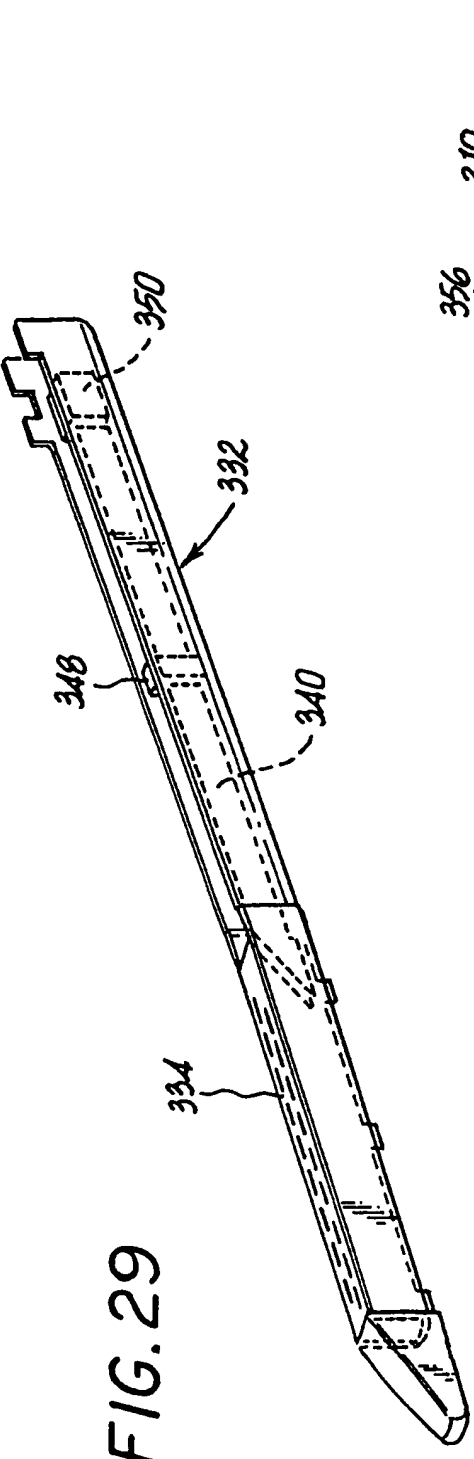


FIG. 28



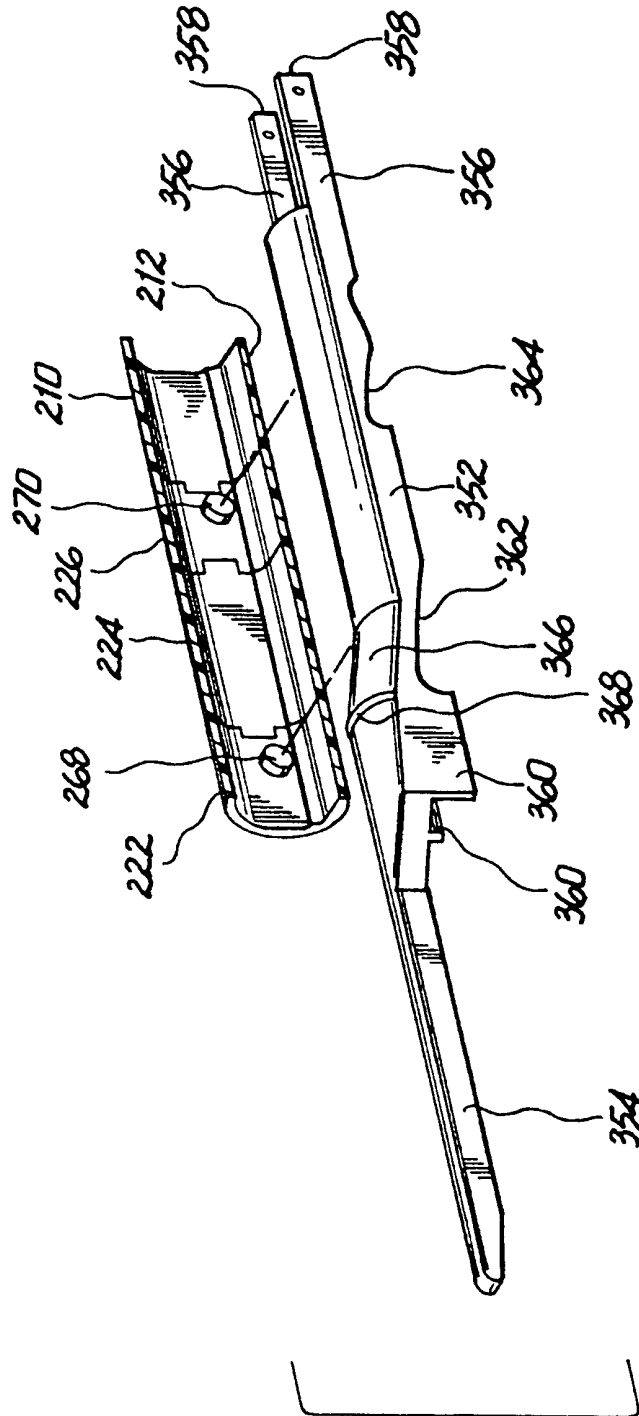


FIG. 31

FIG. 32

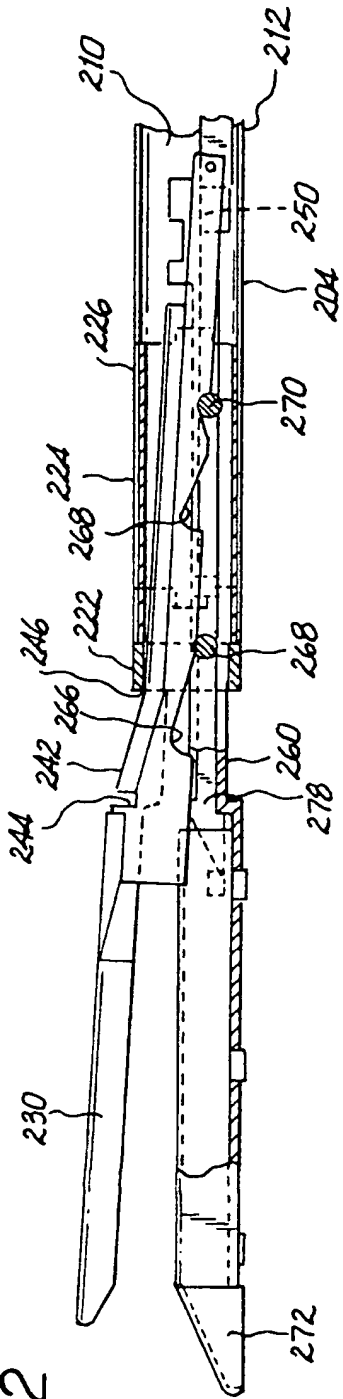


FIG. 33

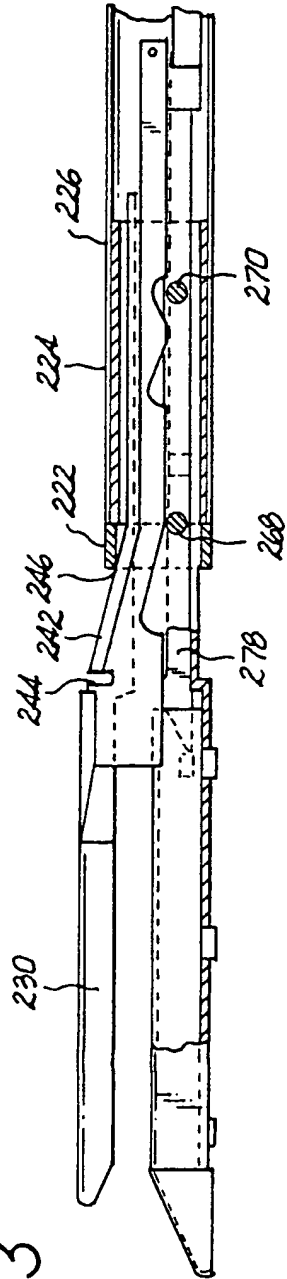
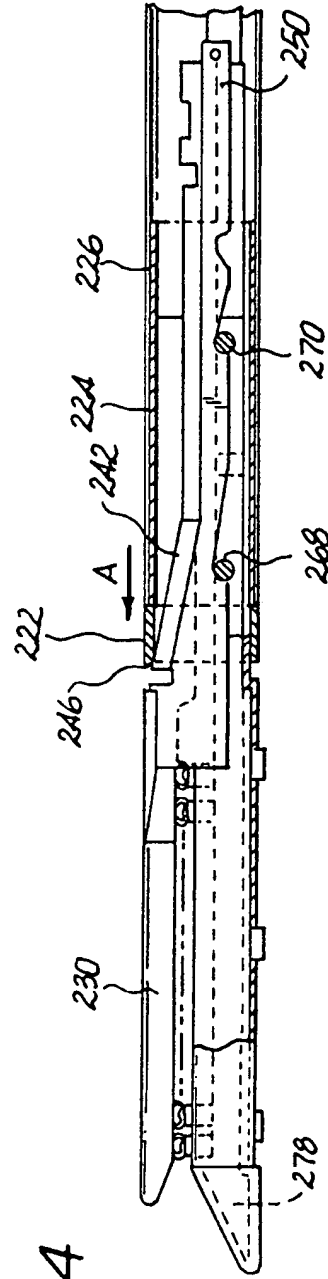


FIG. 34



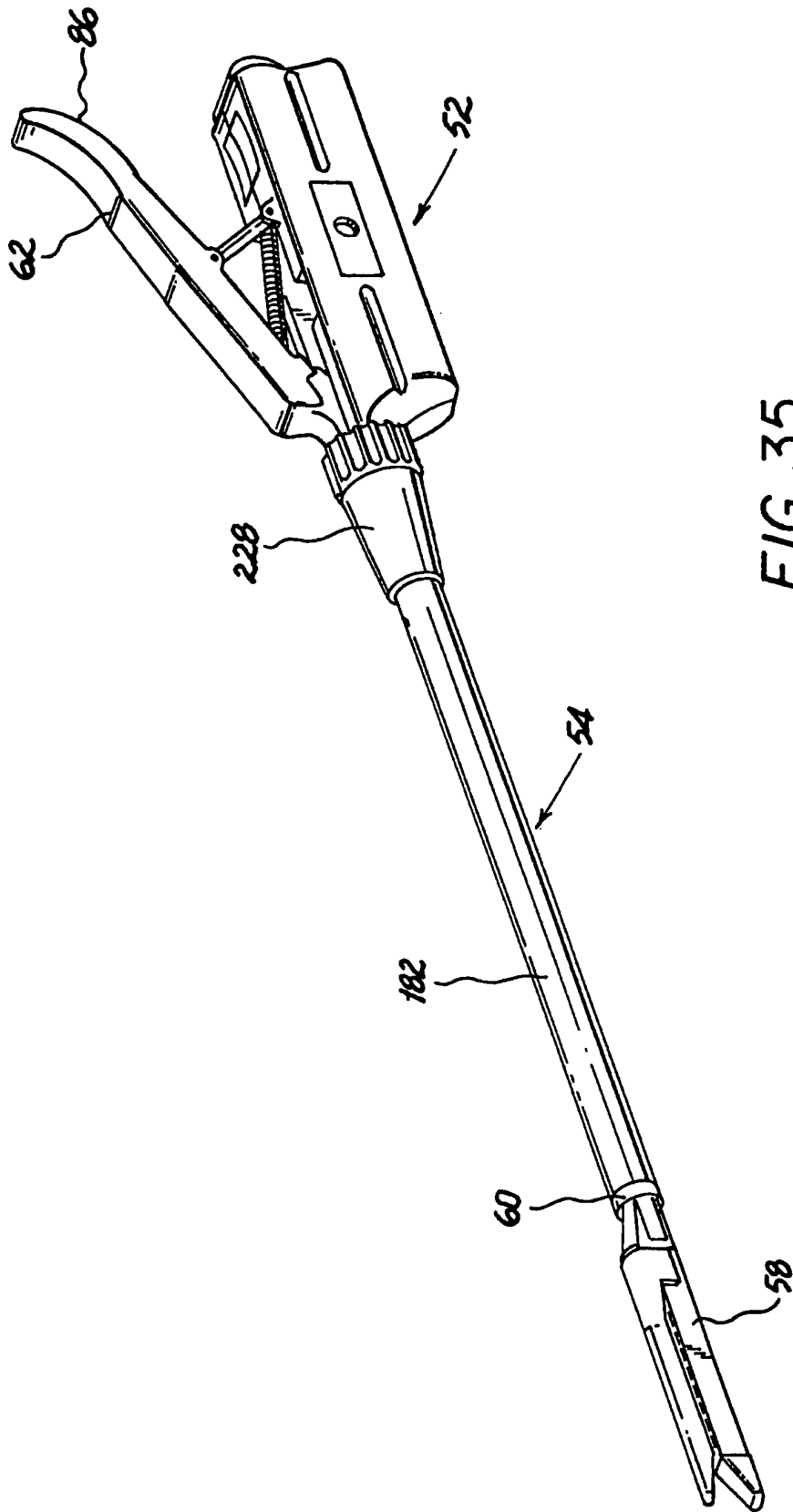
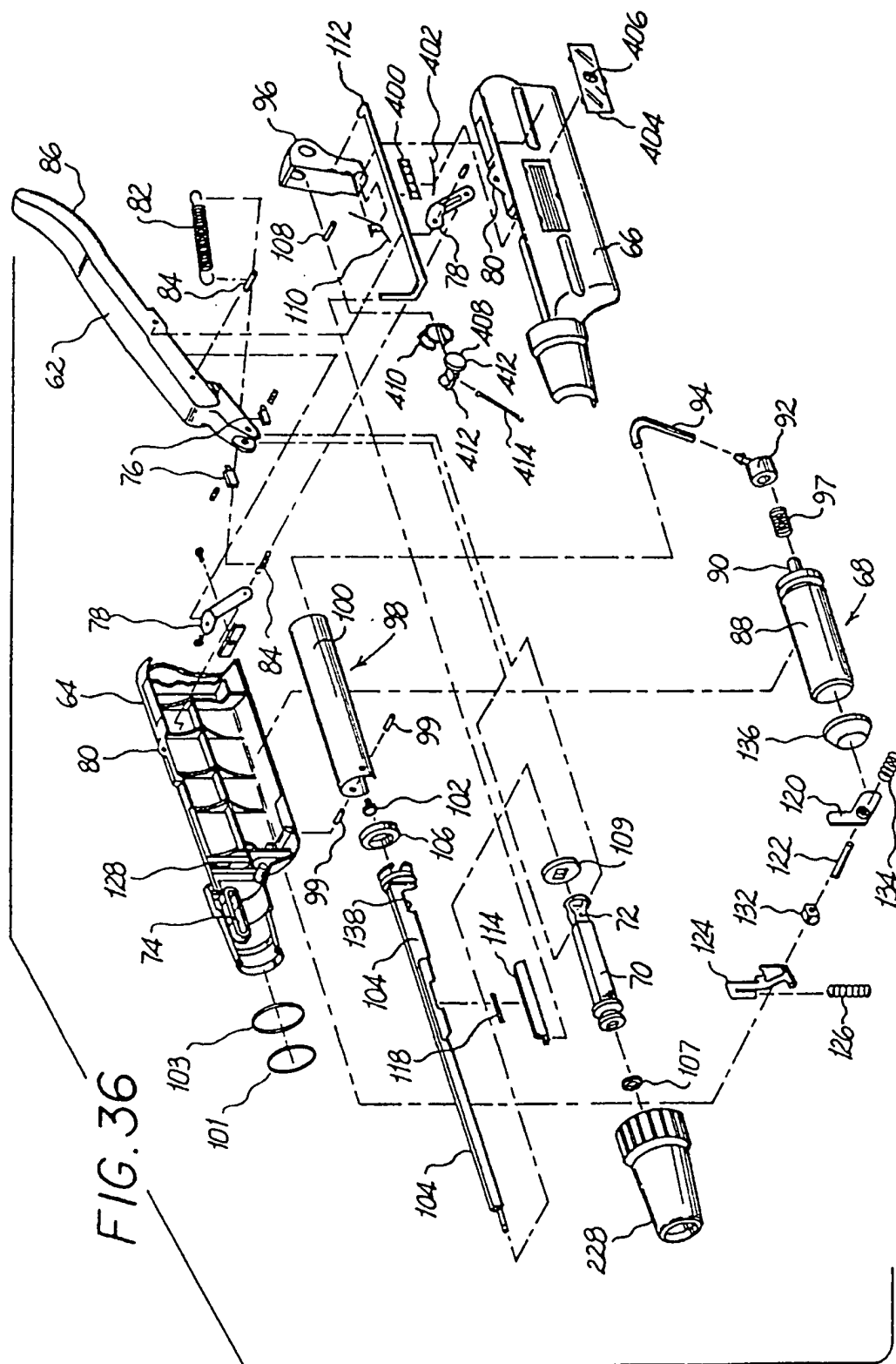
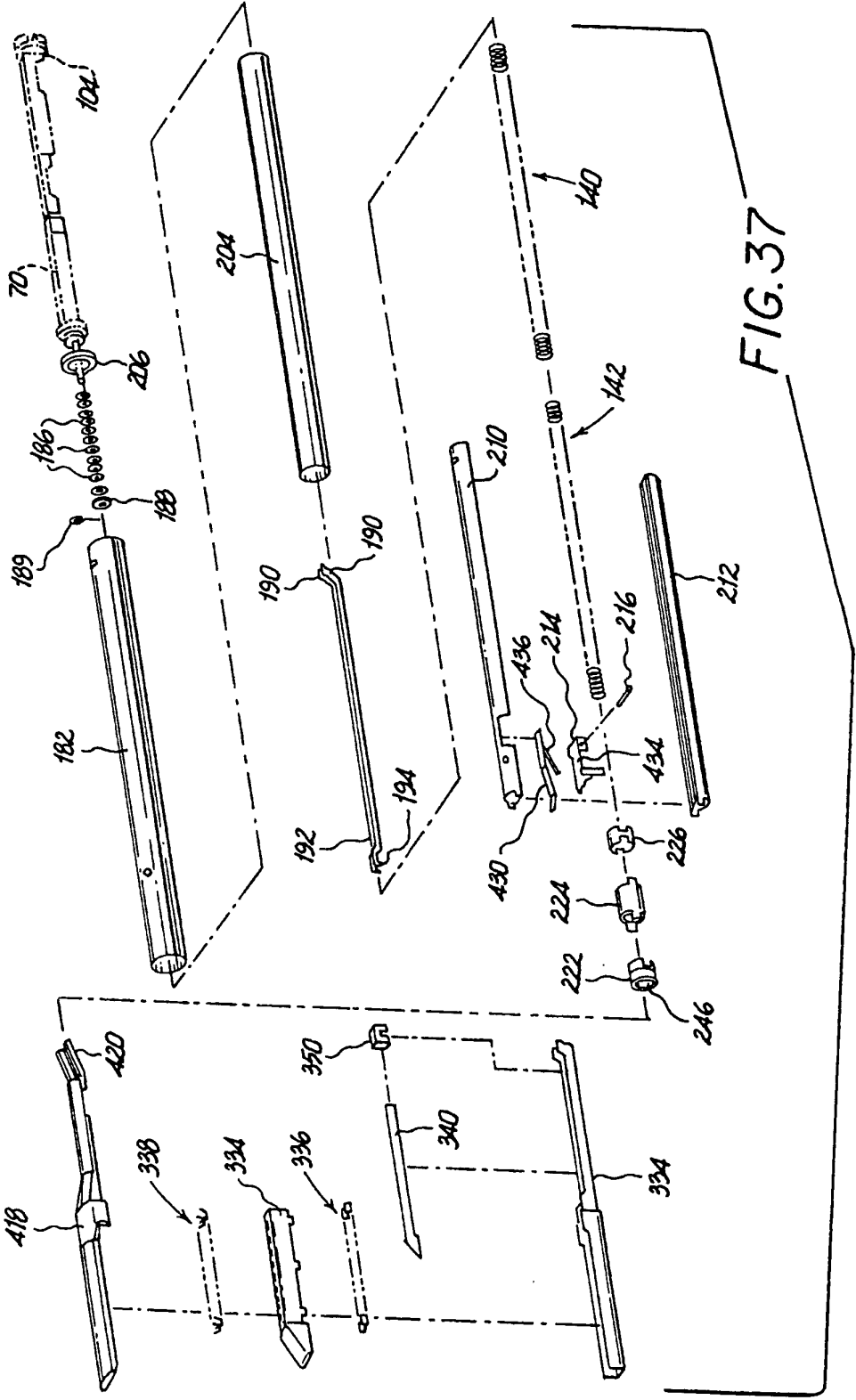
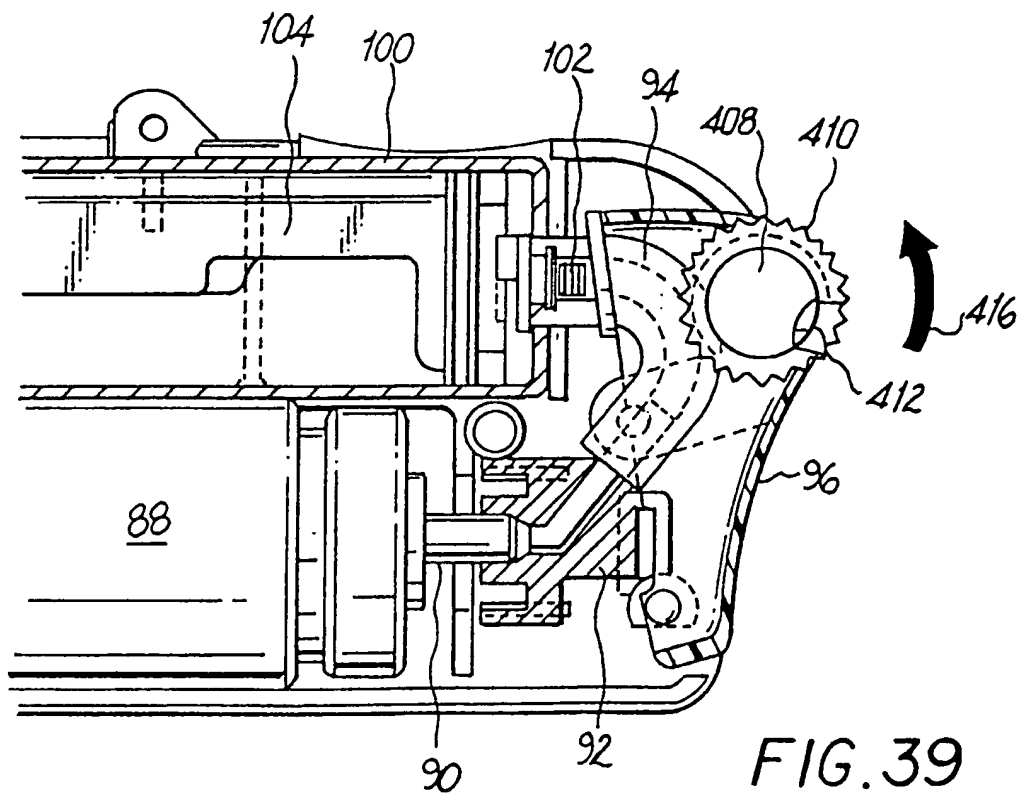
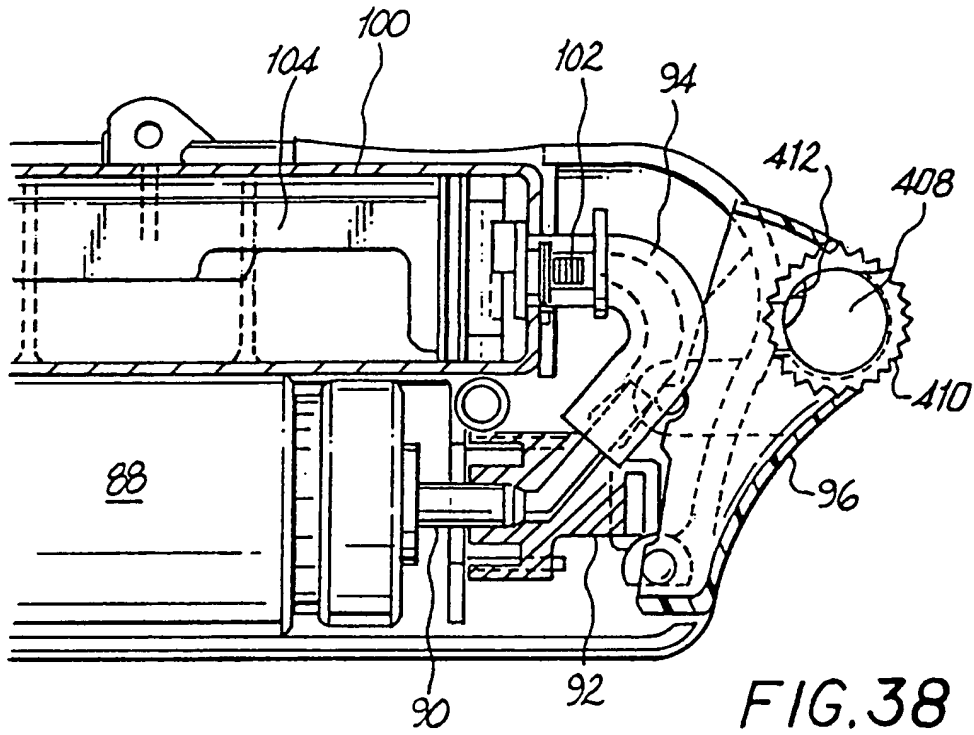


FIG. 35







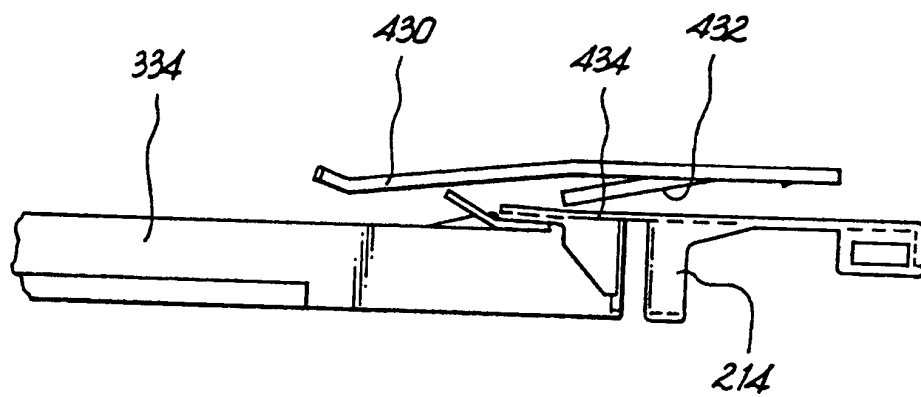


FIG. 40

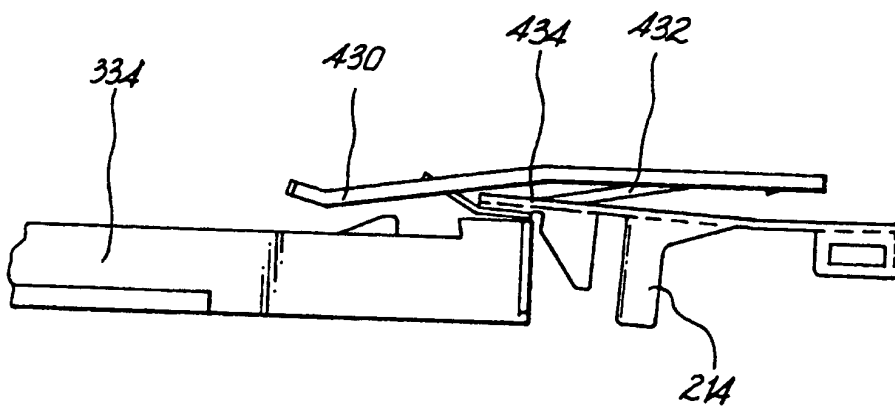
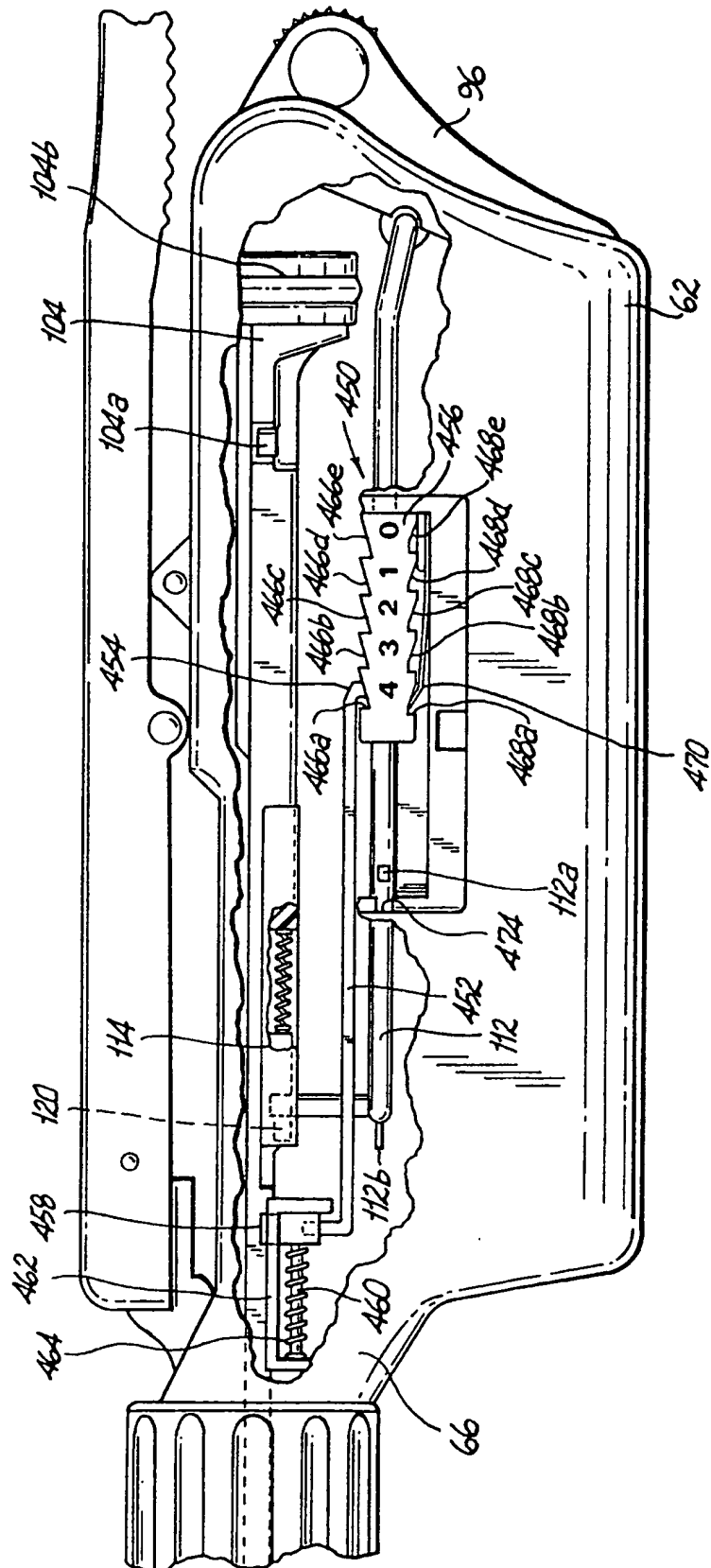


FIG. 41

FIG. 42



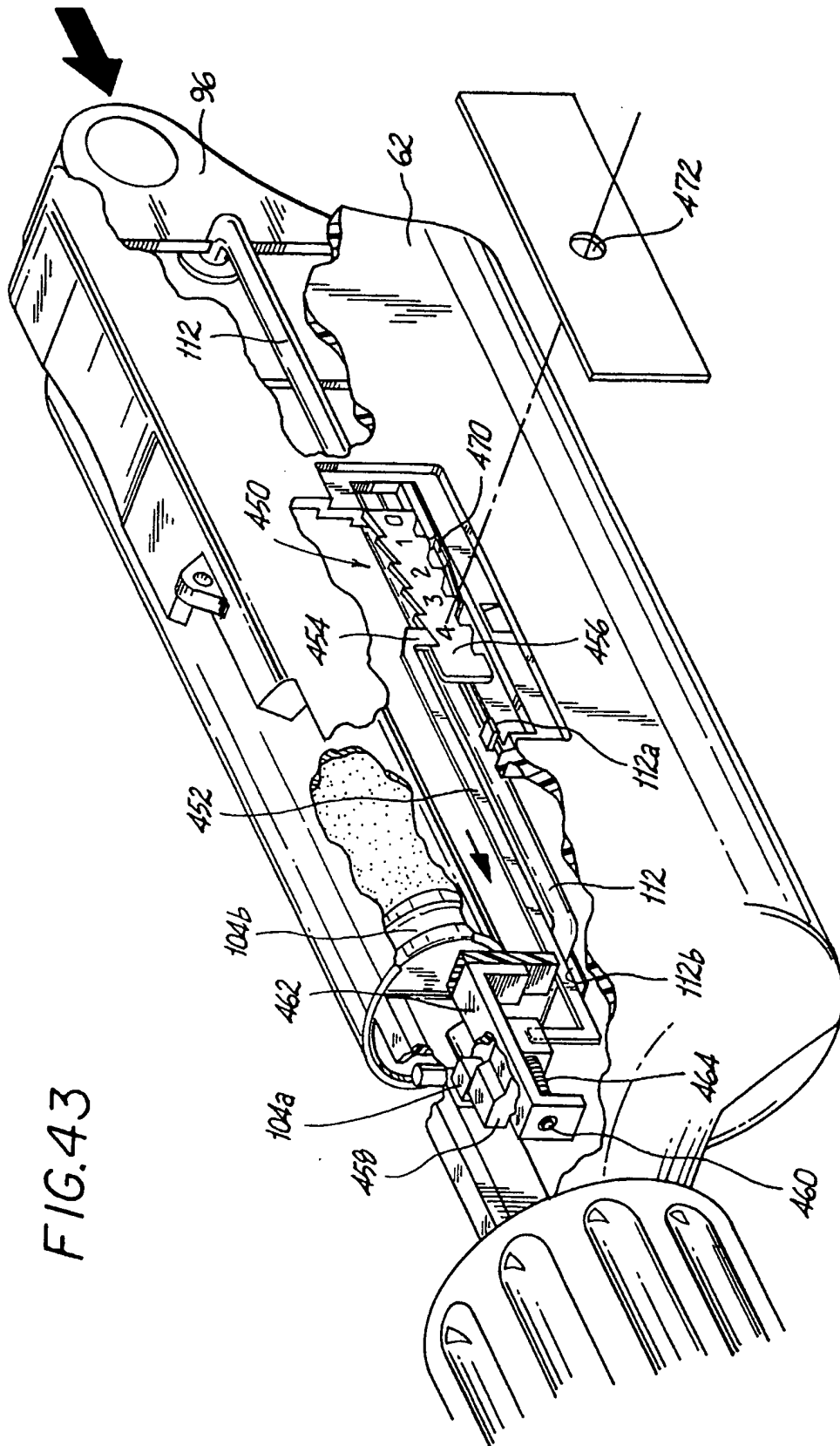


FIG. 43

FIG. 44

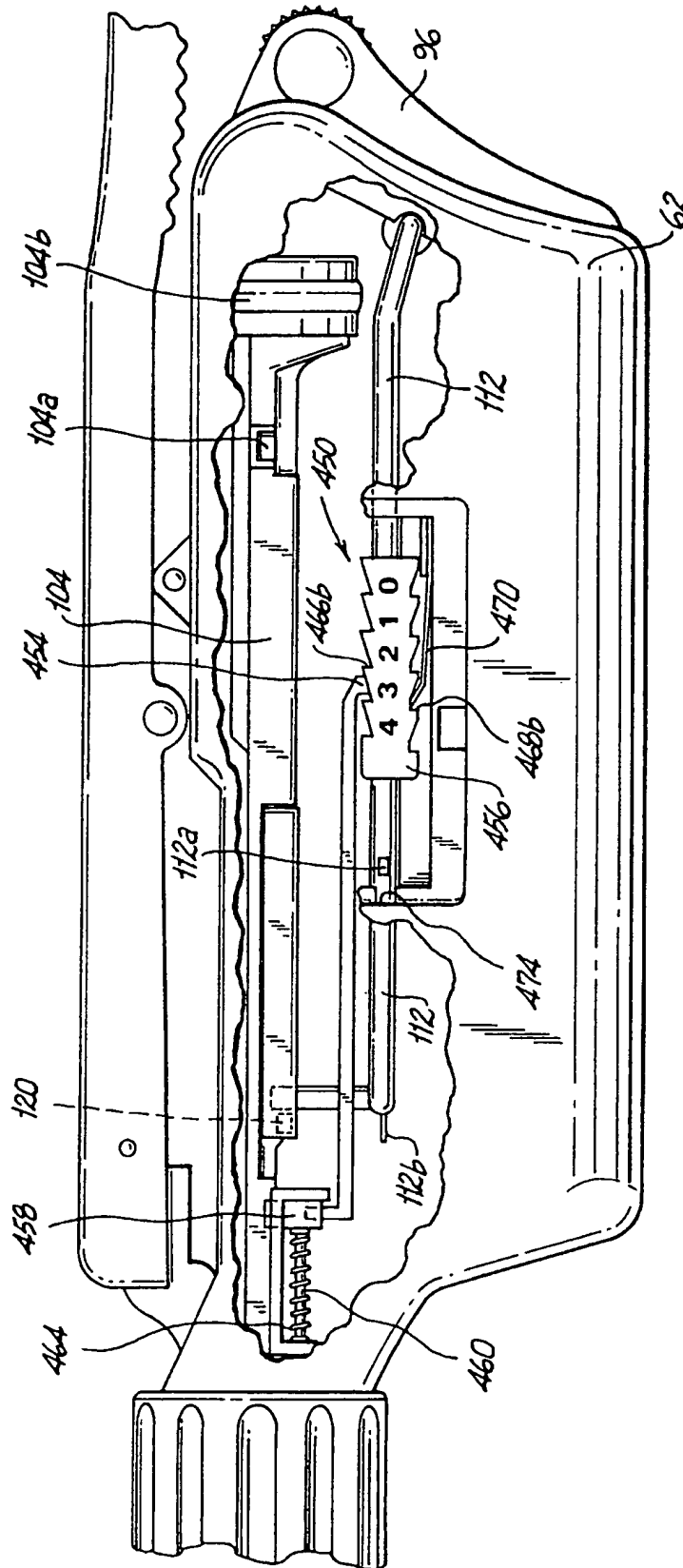


FIG. 45

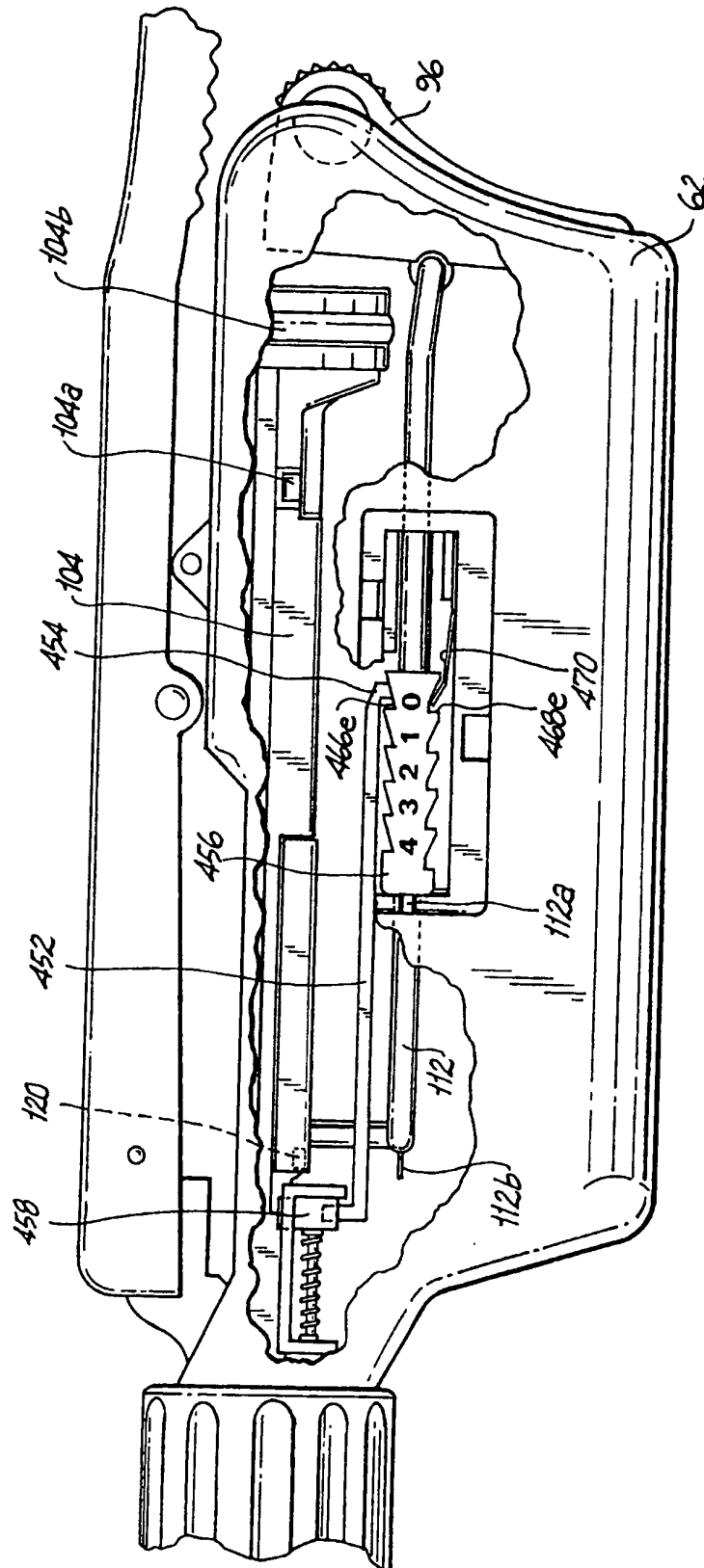


FIG. 46

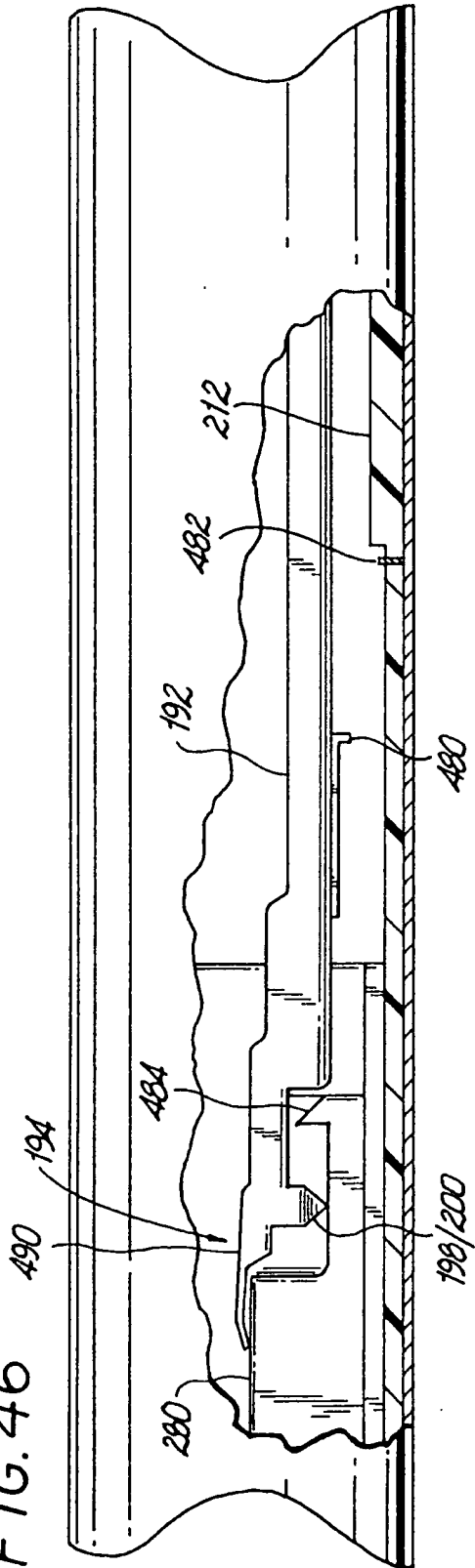
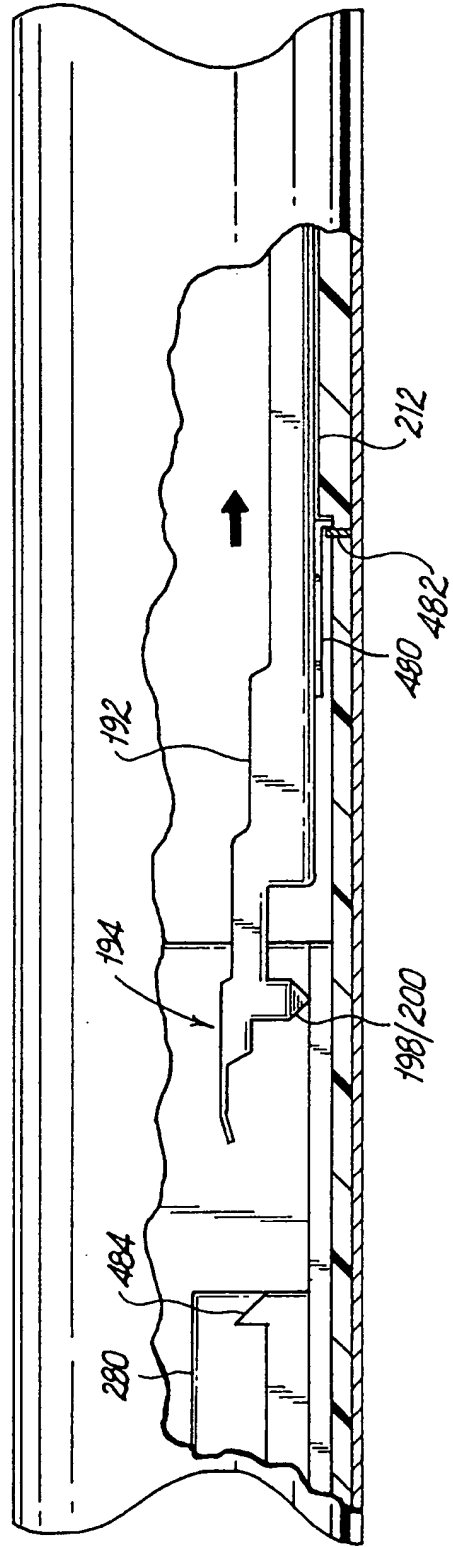
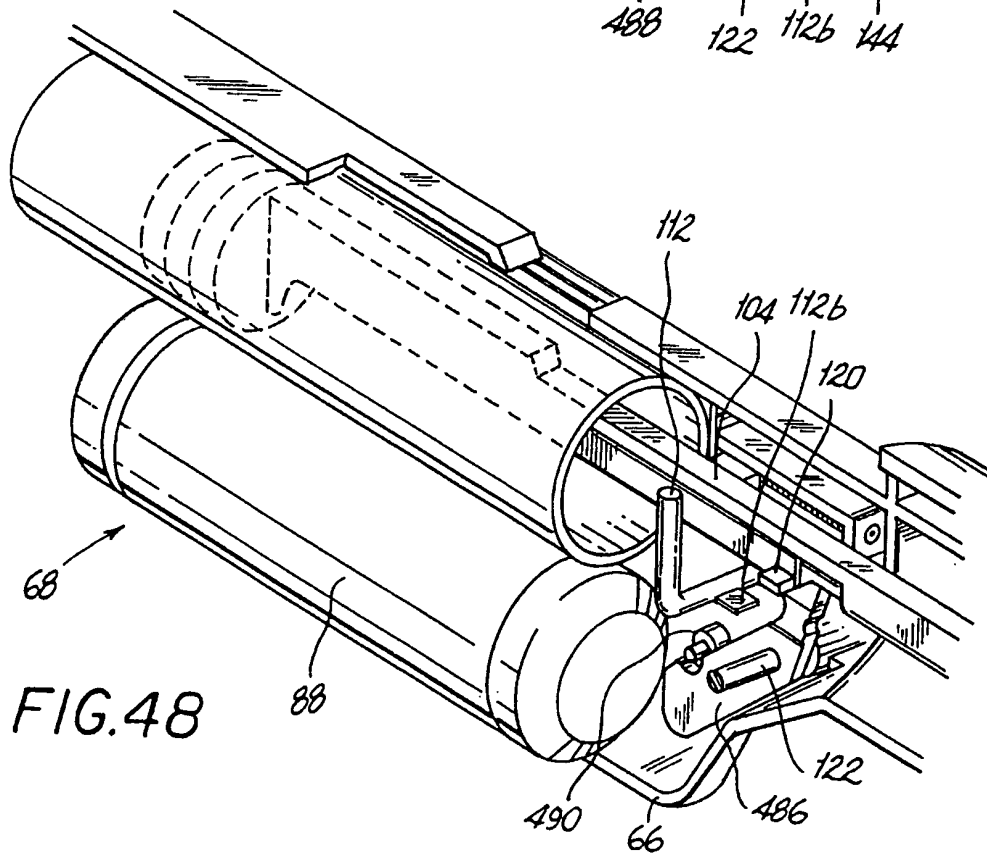
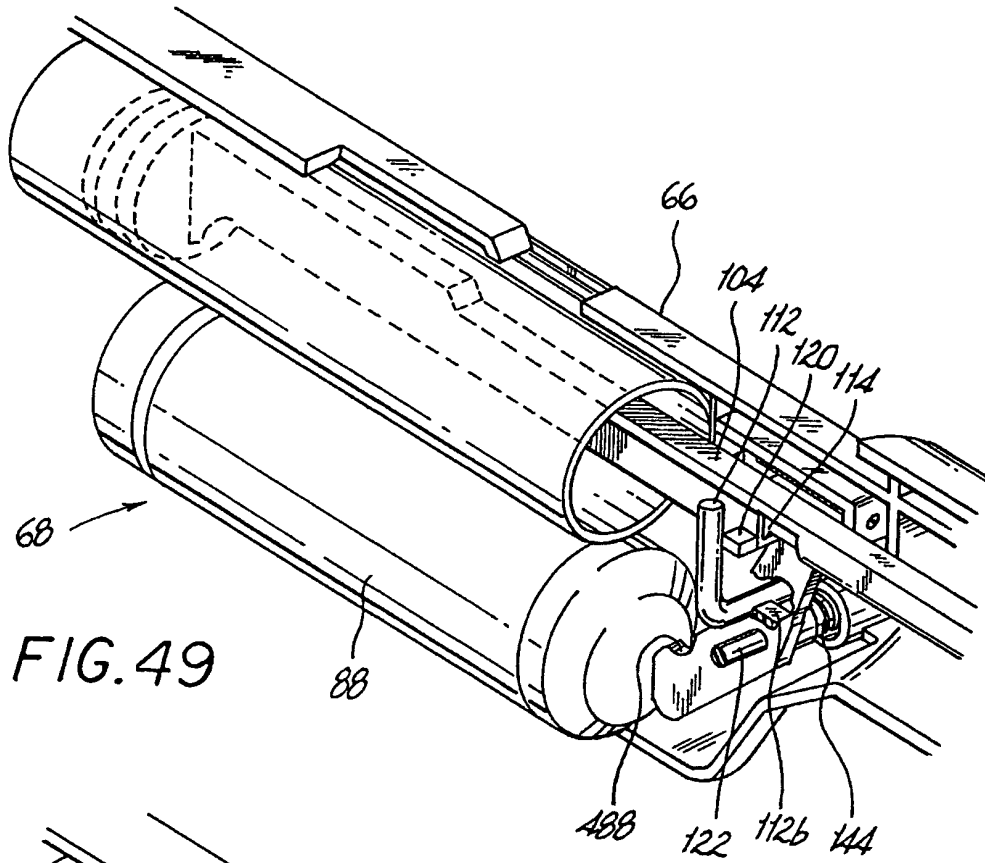


FIG. 47





OTHER ASPECTS OF THE INVENTION

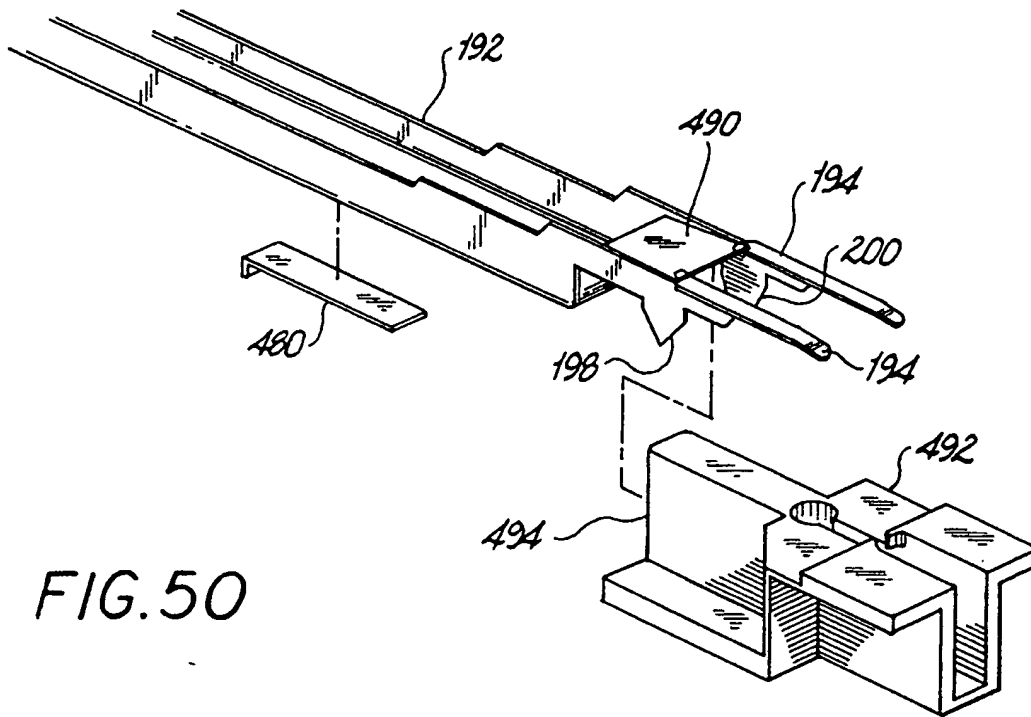


FIG. 50

THIS PAGE BLANK (USPTO)

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USP10)